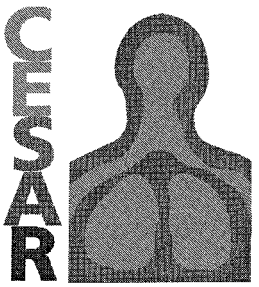
Letter to GPs to allow data access including invoice

CESAR Data Co-ordinating Centre
Medical Statistics Unit
London School of Hygiene & Tropical Medicine
Keppel Street
London WC1E 7HT

tel: 020 7927 2376/2075 fax: 020 7637 2853 website: www.cesar-trial.org



ISRCTN47279827

Conventional Ventilation or
ECMO for
Severe
Adult
Respiratory Failure

address

date

Dear Dr ....

Re XXX (include nhs number if we have it)

As you may remember, the above patient is enrolled in the CESAR trial which aims to compare extra-corporeal membrane oxygenation (ECMO) with conventional treatment in severe respiratory failure. The trial includes follow up at 6 months. Xxxx advised us that he/she does not wish to be interviewed by a researcher but has agreed to us obtaining information from you. I enclose a copy of the signed consent form.

I would be grateful if you or one of your staff could help us by completing the enclosed questionnaire and returning it in the enclosed freepost envelope. Please note we are only interested in health service usage between the dates inserted at the beginning of the questionnaire.

We will pay your practice £40 as an acknowledgement of the work involved on receipt of the completed questionnaire. We will send your practice a proforma invoice to be used on your headed paper.

Yours sincerely

Koro Diallo

Data Management Co-ordinator

steve.robertson@lshtm.ac.uk

Enc: GP questionnaire

Copy of patient consent form

Freepost envelope
Proforma invoice

INVOICE

Reference Number: study number	
CESAR Trial administrative costs	£40.00

Please make the cheque payable to:-

_____

And send to (address):-

_____

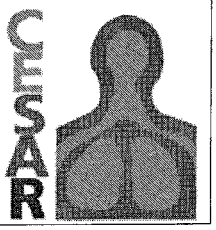
_____

_____

_____

Please return to :-

CESAR Trial Data Co-ordinating Centre
Medical Statistics Unit
London School of Hygiene & Tropical Medicine
Keppel Street
FREEPOST LON20255
London
WC1 7BR

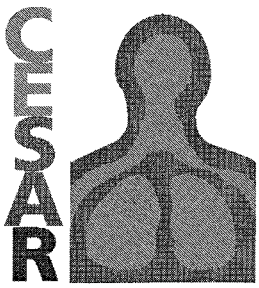


ISRCTN47279827

Access to GP records letter 2

CESAR Data Co-ordinating Centre
Medical Statistics Unit
London School of Hygiene & Tropical Medicine
Keppel Street
London WC1E 7HT

tel: 020 7927 2376/2075 fax: 020 7637 2853 website: www.cesar-trial.org



ISRCTN47279827

Conventional Ventilation or ECMO for Severe Adult Respiratory Failure

address

date

Dear Dr ....

Re XXX (include nhs number if we have it)

As you may remember, the above patient is enrolled in the CESAR trial which aims to compare extra-corporeal membrane oxygenation (ECMO) with conventional treatment in severe respiratory failure. The trial includes follow up at 6 months. Xxxx advised us that he/she does not wish to be interviewed by a researcher but has agreed to us obtaining information from you. I enclose a copy of the signed consent form.

I would be grateful if you or one of your staff could help us by completing the enclosed questionnaire and returning it in the enclosed freepost envelope. Please note we are only interested in health service usage between the dates inserted at the beginning of the questionnaire.

We will pay your practice £40 as an acknowledgement of the work involved on receipt of the completed questionnaire. We will send your practice a proforma invoice to be used on your headed paper.

Yours sincerely

Koro Diallo
Data Management Co-ordinator

steve.robertson@lshtm.ac.uk

Enc: GP questionnaire
Copy of patient consent form
Freepost envelope
Proforma invoice

Follow-up letter to patients

CESAR Data Co-ordinating Centre
Medical Statistics Unit
London School of Hygiene & Tropical Medicine
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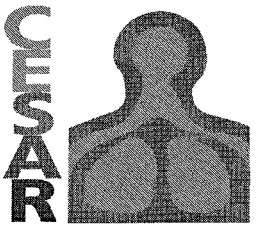


Conventional Ventilation or ECMO for Severe Adult Respiratory Failure

ISRCTN47279827

[patient's address]

date

Dear [name of patient]

I am very pleased that you have been discharged home from hospital following your very serious illness. You may know from discussions with the doctors and nurses and from conversations with family and friends that you were enrolled in the CESAR study when in intensive care. I am now writing to give you more information about CESAR. As it is important that we consider how you are in the longer term, not just while you were in hospital, I am also asking if you will agree to have a follow-up assessment in [month that is 6 months on from date of randomisation]. This assessment is being carried out as patients and researchers feel strongly that it is very important not just to look at the short-term, but also to compare the longer-term health of people who had conventional treatment with those who had ECMO. It is very important that we follow up as many patients as possible as it is only by doing this that we will be able to tell which method of treatment is better.

Information about the study is set out below.

Why are you in the CESAR study?

As you were so seriously ill with breathing problems, the doctors were concerned that you might not survive. In cases such as yours it is not clear what the best treatment should have been. There are two possible treatments that could have been used, conventional ventilation and ECMO. There is an urgent need for new treatments. These have to be compared with the treatment that is normally used to make sure we only introduce new treatments that are a real improvement. Since we did not really know which of these two treatments would be better for you we asked permission from your relatives to include you in a study to try to find the answer.

What is the study trying to find out?

The study is comparing two ways of looking after patients with serious breathing problems.

- One way uses a ventilator to push oxygen into the lungs. We call this conventional ventilation, as it is the most common method.
- The other way uses a system called ECMO to by-pass the lungs. This is only available in one place (Leicester), and only available for the study.

At this time, we do not know if conventional ventilation is better or worse than ECMO for patients with serious breathing problems. This study is designed to help decide the best way of caring for patients with these problems so that more patients survive.

Patients from many hospitals in the UK are taking part in this NHS study which has been given research ethics committee approval. The introductory information sheet which was given to your relatives is in the pack with this letter for your information.

What happened to you as a result of being in the study?

Since we do not know which treatment is the better:

- Half the patients in the study were treated on a ventilator.
- The other half were transferred to Glenfield Hospital, Leicester to be considered for ECMO.

Once you were included in the study, neither you nor the doctors were able to choose which of these two methods was offered. Instead, this decision was made randomly and depended on chance (so-called random assignment). This element of chance is important so that the two methods can be tested fairly. Following entry into the study you were allocated [allocation]. Further information about [allocated treatment] is in the pack with this letter.

What happens now?

We plan to follow-up all patients at about six months following their entry into the study. If you agree, we will contact you again to make an appointment for a researcher working with this study to find out about your state of health. The researcher will not be medically qualified, but is professionally qualified to undertake the assessment. This assessment will take about an hour and will take place at your home (or elsewhere if this is more convenient for you).

I hope that you will agree to continue in the study. If you do not wish to be visited at home, we could arrange a telephone interview, or send the questionnaires through the post. These methods would provide us with less information, especially about your physical state, so I very much hope that you will agree to be interviewed 'face to face' at home. We would also like to obtain information about your care from your GP, and we need your permission to do this.

It is possible that we will be funded to conduct additional, longer term follow-up assessments. So that we do not lose contact with you we are asking for your agreement to send your name to an organisation called the NHS Central Register (based at the General Register Office) that holds the name of the area where you are registered with a GP. This will help us to keep in contact with you in the future. If you agree, you will not need to do anything except to tick the appropriate box on the enclosed reply slip.

In addition to all the other issues you have had to face, we are aware that illness may lead people to have extra costs. We want to understand how much your illness cost you and your family, so the researcher will also ask you about this. As an aid to your memory we have included an Events Diary which you might like to complete from the time of discharge from hospital until the assessment. Of course, all information that we collect from health service notes and directly from you and the people caring for you will be treated in the strictest confidence.

I should be very pleased if you would return the enclosed reply slip (in the freepost envelope) letting me know whether you wish or do not wish to have a follow-up visit. If you agree, the researcher will contact you in [2 months prior to visit] to arrange a time that is mutually convenient for your assessment.

We will keep you informed about the progress of the study each year unless you say that you do not want this information. When the study finishes we will ask if you would like to have a summary of the study results.

If you have any questions about CESAR or the NHS Central Register please do not hesitate to contact me.

Yours sincerely

Steven Robertson

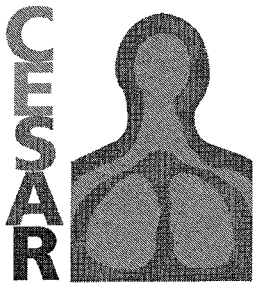
Data Management Co-ordinator

Enc: reply slip

freepost envelope

CESAR Information Pack (Events Diary, Introductory information, Information for relatives if allocation is to (allocated treatment)

Conventional Ventilation or
ECMO for
Severe
Adult
Respiratory Failure



Agreement to participation in follow-up and access to information from your GP and the Central Register

Please complete and return this reply slip in the freepost envelope provided

Please amend or add to these details if they are wrong or incomplete

Name:	**GP's name:**
Address: (including postcode)	**GP's Address:** (including postcode)
Tel. number:	**GP's tel. number:**
NHS number: (if known)	

(Please tick appropriate box)	YES	NO
I agree to be visited at home	☐	☐
I do not wish to be assessed at home but agree to the following:	☐	☐
• A telephone interview	☐	☐
• A postal questionnaire	☐	☐
I agree to information being obtained from my GP records		
I agree for CESAR to request details from the NHS Central Register in order to keep in touch with me at a later date and to follow-up my health status	☐	☐
I would like to receive annual updates about the study	☐	☐

I would like to be asked at the end of the study whether I wish to see the results ☐ ☐

If you have agreed to any part of the follow-up please let us know how you would like us to contact you to make arrangements in the future (please tick as appropriate):

Post ☐

Telephone ☐

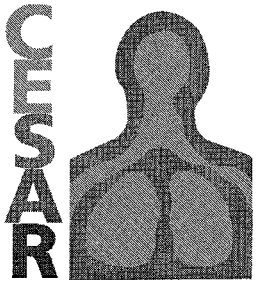
Email (please provide address) _____ ☐

Signature:_____ Date: ☐☐ ☐☐ ☐☐☐☐ dd/mm/yyyy

Follow-up letter to GPs

CESAR Data Co-ordinating Centre
Medical Statistics Unit
London School of Hygiene & Tropical Medicine
Keppel Street
London WC1E 7HT

tel: 020 7927 2376/2075 fax: 020 7637 2853 website: www.cesar-trial.org



ISRCTN47279827

Conventional Ventilation or
ECMO for
Severe
Adult
Respiratory Failure

[GP address]

Date

Dear [name will be personalised]

Re: [patient's name, dob: dd/mm/yyyy , CESAR study number]

[Patients's name] was recruited into The CESAR Trial on [date of randomisation at hospital]. Copies of the information leaflets which were given to [*patient's name*] relative prior to trial entry are enclosed as well as a copy of the letter which has been sent to [*patient's name]* following his/her discharge home on [*date of discharge*]. The patient's relative's assent included agreement to random allocation, access to records and follow-up at six months. However, we will only make further contact with [*patient's name*] when she/he has returned the reply slip with permission to follow-up.

All of the patients recruited into the trial were severely ill, and we will not necessarily know about their health status after they leave hospital. We will therefore want to check first that the six-month follow up is appropriate for the family at any particular time before arranging for a researcher to assess [*patient's name]* at home. The researcher is not medically qualified, but is professionally qualified to undertake the assessment. The researcher will therefore contact you shortly before this assessment is due to ask if there are any reasons why he/she should not contact [*patient's name*] to make arrangements for the assessment. Please would you check that we have the correct contact details. If the patient has directly contacted the CESAR trial office shortly before the follow-up assessment is due, the GP will not be contacted.

Please return the reply slip using the enclosed freepost envelope. Alternatively you can fax it on 020 7637 2853, or send an email message to steve.robertson@lshtm.ac.uk.

We will also be registering *[patient's name]* on the NHS central register for possible later follow-up providing she/he gives us permission to do so. We will be asking *[patient's name]* for his/her NHS number to facilitate this, but it would be very helpful if you would provide this on the reply slip in case he/she cannot easily find it.

If you wish, we will send you the results of the trial when it is completed – please indicate on the reply slip if this would be of interest to you.

If you have any questions about the enclosed, or would like any further information, please do not hesitate to get in touch with us.

With many thanks for your time and assistance.

Yours sincerely

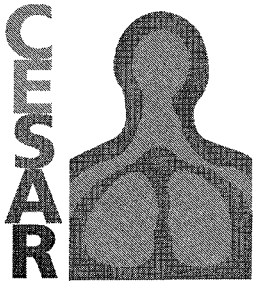
Steven Robertson

Data Management Co-ordinator

Enc: Reply slip
Copy of letter to patient

Information for relatives (introductory and allocation)
Freepost envelope

Conventional Ventilation or
ECMO for
Severe
Adult
Respiratory Failure



GP's name: Add details
Address: Add details

Patient's name, dob: dd/mm/yyyy, CESAR study number

1. I am the GP for the above named patient.

   Yes ☐ (go to question 3)

   No ☐ (go to question 2)

2. The GP responsible for this patient is:

   Name: _____

   Address: _____

   Postcode: _____ Telephone: _____

   Thank you. Please now return this slip in the enclosed envelope

3. The following contact information for [patient's name] is correct/incorrect (please delete as applicable and amend the information below if required).

   Name: Add details
   Address: Add details

4 [Patient's name] NHS number is:_____

5. I would like to receive a copy of the CESAR Trial report when it is available

Yes ☐ No ☐

6. I would like to receive copies of the CESAR newsletter Yes ☐ No ☐

Thank you. Please now return this slip in the enclosed envelope to:

The CESAR Trial Data Co-ordinating Centre, Medical Statistics Unit

London School of Hygiene and Tropical Medicine

Keppel Street LONDON WC1E 7HT

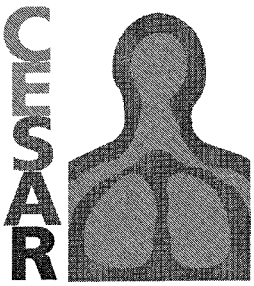
Or fax 020 7637 2853

www. cesar-trial.org

Letter of thanks to patients

CESAR Data Co-ordinating Centre
Medical Statistics Unit
London School of Hygiene & Tropical Medicine
Keppel Street
London WC1E 7HT

tel: 020 7927 2376/2075 fax: 020 7637 2853 website: www.cesar-trial.org



ISRCTN47279827

Conventional Ventilation or ECMO for Severe Adult Respiratory Failure

Name

Address

Date

Dear [patient's name]

Many thanks for participating in the follow-up assessment of the CESAR study on [date of visit] with [researcher name], our study researcher. Information obtained will be very helpful in determining which treatment for respiratory failure is better.

Now that you have had your follow-up assessment we would like to know if you are interested in receiving an annual update on the study and its final results. Although we asked you this in the letter we sent when you were discharged home from hospital we felt we should ask you again now that your assessment has taken place.

I am enclosing a reply slip for you to let us know whether you wish to continue receiving information about CESAR, and would be grateful if you could complete this and return it to our Data Co-ordinating Centre in London in the enclosed freepost envelope.

Once again many thanks for your help, and best wishes for the future.

Yours sincerely

Steven Robertson

Data Management Co-ordinator

Tel: 020 7927 2075

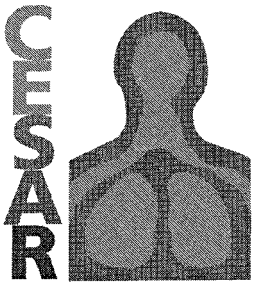
Fax: 020 7637 2853

steve.robertson@lshtm.ac.uk

Enc: Reply slip

Freepost envelope

Conventional Ventilation or
ECMO for
Severe
Adult
Respiratory Failure



Please complete/amend if necessary

Patients name
Address
Postcode
Phone
CESAR study number

I would like to receive annual updates on CESAR Yes ☐ No ☐

I would like to be asked if I want to see the final results when they are available Yes ☐ No ☐

Signature:_____

Date: ☐☐ ☐☐ ☐☐☐☐

Please complete this reply slip and return in the freepost envelope to:

CESAR Data Co-ordinating Centre, Medical Statistics Unit
London School of Hygiene & Tropical Medicine
Keppel Street, London WC1E 7HT

Telephone: 020 7927 2376/2075

Letter to patients allocated to treatment group who did not receive ECMO

CESAR Data Co-ordinating Centre
Medical Statistics Unit
London School of Hygiene & Tropical Medicine
Keppel Street
London WC1E 7HT

tel: 020 7927 2376/2075 fax: 020 7637 2853 website: www.cesar-trial.org

Conventional Ventilation or ECMO for Severe Adult Respiratory Failure

[name/address]

[date]

Dear [patient name]

I am very pleased that you have been discharged home from hospital following your very serious illness. You may know from discussions with the doctors and nurses and from conversations with family and friends that you were enrolled in the CESAR study when in intensive care. I am now writing to give you more information about CESAR. As it is important that we consider how you are in the longer term, not just while you were in hospital, I am also asking if you will agree to have a follow-up assessment in [date 6 months post randomisation]. This assessment is being carried out as patients and researchers feel strongly that it is very important not just to look at the short-term, but also to compare the longer-term health of people who had conventional treatment with those who had ECMO. It is very important that we follow up as many patients as possible as it is only by doing this that we will be able to tell which method of treatment is better.

Information about the study is set out below.

Why are you in the CESAR study?

As you were so seriously ill with breathing problems, the doctors were concerned that you might not survive. In cases such as yours it is not clear what the best treatment should have been. There are two possible treatments that could have been used, conventional ventilation and ECMO. There is an urgent need for new treatments. These have to be compared with the treatment that is normally used to make sure we only introduce new treatments that are a real improvement. Since we did not really know which of these two treatments would be better for you we asked permission from your relatives to include you in a study to try to find the answer.

What is the study trying to find out?

The study is comparing two ways of looking after patients with serious breathing problems.

- One way uses a ventilator to push oxygen into the lungs. We call this conventional ventilation, as it is the most common method.
- The other way uses a system called ECMO to by-pass the lungs. This is only available in one place (Leicester), and only available for the study.

At this time, we do not know if conventional ventilation is better or worse than ECMO for patients with serious breathing problems. This study is designed to help decide the best way of caring for patients with these problems so that more patients survive.

Patients from many hospitals in the UK are taking part in this NHS study which has been given research ethics committee approval. The introductory information sheet which was given to your relatives is in the pack with this letter for your information.

What happened to you as a result of being in the study?

Since we do not know which treatment is the better:

- Half the patients in the study were treated on a ventilator.
- The other half were transferred to Glenfield Hospital, Leicester to be considered for ECMO.

Once you were included in the study, neither you nor the doctors were able to choose which of these two methods was offered. Instead, this decision was made randomly and depended on chance (so-called random assignment). This element of chance is important so that the two methods can be tested fairly. Following entry into the study you were allocated to consideration for ECMO. Further information about ECMO was given to your relatives at the time you were entered into the trial, and a copy is included in the pack with this letter. However, due to your condition improving when you arrived in Leicester it was decided not to start ECMO treatment, and conventional ventilatory management was continued. I have also enclosed information about this treatment.

What happens now?

We plan to follow-up all patients at about six months following their entry into the study. If you agree, we will contact you again to make an appointment for a researcher working with this study to find out about your state of health. The researcher will not be medically qualified, but is professionally qualified to undertake the assessment. This assessment will take about an hour and will take place at your home (or elsewhere if this is more convenient for you).

I hope that you will agree to continue in the study. If you do not wish to be visited at home, we could arrange a telephone interview, or send the questionnaires through the post. These methods would provide us with less information, especially about your physical state, so I very much hope that you will agree to be interviewed 'face to face' at home. We would also like to obtain information about your care from your GP, and we need your permission to do this.

It is possible that we will be funded to conduct additional, longer term follow-up assessments. So that we do not lose contact with you we are asking for your agreement to send your name to an organisation called the NHS Central Register (based at the General Register Office) that holds the name of the area where you are registered with a GP. This will help us to keep in contact with you in the future. If you agree, you will not need to do anything except to tick the appropriate box on the enclosed reply slip.

In addition to all the other issues you have had to face, we are aware that illness may lead people to have extra costs. We want to understand how much your illness cost you and your family, so the researcher will also ask you about this. As an aid to your memory we have included an Events Diary which you might like to complete from the time of discharge from hospital until the assessment. Of course, all information that we collect from health service notes and directly from you and the people caring for you will be treated in the strictest confidence.

I should be very pleased if you would return the enclosed reply slip (in the freepost envelope) letting me know whether you wish or do not wish to have a follow-up visit. If you agree, the researcher will contact you in [date 2 months before assessment date] to arrange a time that is mutually convenient for your assessment.

We will keep you informed about the progress of the study each year unless you say that you do not want this information. When the study finishes we will ask if you would like to have a summary of the study results.

If you have any questions about CESAR or the NHS Central Register please do not hesitate to contact me.

Yours sincerely

Steven Robertson

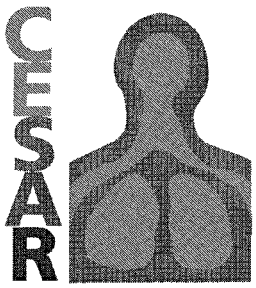
Data Management Co-ordinator

Enc: reply slip

freepost envelope

CESAR Information Pack (Events Diary, Introductory information, Information for relatives if allocation is to ECMO, Information for relatives if allocation is to conventional ventilation)

Conventional Ventilation or
ECMO for
Severe
Adult
Respiratory Failure



Agreement to participation in follow-up and access to information from your GP and the Central Register

Please complete and return this reply slip in the freepost envelope provided

Please amend or add to these details if they are wrong or incomplete

Name:	**GP's name:**
Address: (including postcode)	**GP's Address:** (including postcode)
Tel. number:	**GP's tel. number:**
NHS number: (if known)	

(Please tick appropriate box)	Yes	No
I agree to be visited at home	☐	☐
I do not wish to be assessed at home but agree to the following:		
• A telephone interview	☐	☐
• A postal questionnaire	☐	☐
I agree to information being obtained from my GP records	☐	☐
I agree for CESAR to request details from the NHS Central Register in order to keep in touch with me at a later date and to follow-up my health status	☐	☐
I would like to receive annual updates about the study	☐	☐
I would like to be asked at the end of the study whether I wish to see the results	☐	☐

If you have agreed to any part of the follow-up please let us know how you would like us to contact you to make arrangements in the future (please tick as appropriate):

Post ☐

Telephone ☐

Email (please provide address) _____ ☐

Signature:_____ Date: ☐☐ ☐☐ ☐☐☐☐ dd/mm/yyyy

Patient reminder letter 1

CESAR Data Co-ordinating Centre
Medical Statistics Unit
London School of Hygiene & Tropical Medicine
Keppel Street
London WC1E 7HT

tel: 020 7927 2376/2075 fax: 020 7637 2853 website: www.cesar-trial.org

Conventional Ventilation or ECMO for Severe Adult Respiratory Failure

ISRCTN47279827

[address]

[date]

Dear [patient name]

Re: 6-month follow up

You may remember that I wrote to you following your discharge from hospital to see whether you would be willing to be assessed 6 months after you were enrolled in the CESAR study. I enclose a copy of my original letter.

As I have not received a reply and the time for your assessment is getting close, I am writing again to see if you are willing to take part. This assessment is being carried out as patients and researchers feel strongly that it is very important not just to look at the short-term, but also to compare the longer-term health of people who had conventional treatment with those who had ECMO. It is very important that we follow up as many patients as possible as it is only by doing this that we will be able to tell which method of treatment is better.

The assessment would take place in your home. It includes questions about your general health and quality of life, a 'blowing test' to examine your lung function, and an examination of your arm movement. It would take approximately one hour, and can be arranged at a time and date convenient to you.

If you do not wish to be assessed at home, we could arrange a telephone interview, or send the questionnaires through the post. We would also like to obtain information from your GP, and need your permission to do this.

These methods would provide us with less information, especially about your physical state, so I very much hope that you will agree to be interviewed at home, and enclose a reply slip to be returned in the enclosed freepost envelope. If you have any questions please do not hesitate to contact me.

It is possible that we will be funded to conduct additional, longer term follow-up assessments. So that we do not lose contact with you we are asking for your agreement to send your name to an organisation called the NHS Central Register (based at the General Register Office) that holds the name of the area where you are registered with a GP. This will help us to keep in contact with you in the future. If you agree, you will not need to do anything except to tick the appropriate box on the enclosed reply slip.

Yours sincerely

Steven Robertson

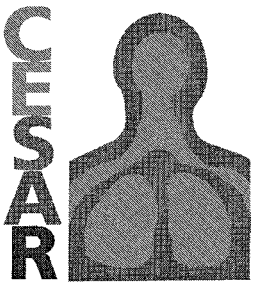
Data Management Co-ordinator

Enc: Reply slip

Copy of letter sent at discharge

Freepost envelope

Conventional Ventilation or
ECMO for
Severe
Adult
Respiratory Failure



Agreement to participation in follow-up and access to information from your GP and the Central Register

Please complete and return this reply slip in the freepost envelope provided

Please amend or add to these details if they are wrong or incomplete

Name:	**GP's name:**
Address: (including postcode)	**GP's Address:** (including postcode)
Tel. number:	**GP's tel. number:**
NHS number: (if known)	

(Please tick appropriate box)

	Yes	No
I agree to be visited at home	☐	☐
I do not wish to be assessed at home but agree to the following:		
• A telephone interview	☐	☐
• A postal questionnaire	☐	☐
I agree to information being obtained from my GP records	☐	☐
I agree for CESAR to request details from the NHS Central Register in order to keep in touch with me at a later date and to follow-up my health status	☐	☐

	YES	NO
I would like to receive annual updates about the study	☐	☐
I would like to be asked at the end of the study whether I wish to see the results	☐	☐

If you have agreed to any part of the follow-up please let us know how you would like us to contact you to make arrangements in the future (please tick as appropriate):

Post ☐

Telephone ☐

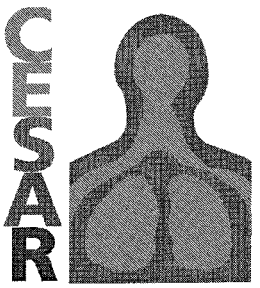
Email (please provide address) _____ ☐

Signature:_____ Date: ☐☐ ☐☐ ☐☐☐☐ dd/mm/yyyy

Patient reminder letter 2

CESAR Data Co-ordinating Centre
Medical Statistics Unit
London School of Hygiene & Tropical Medicine
Keppel Street
London WC1E 7HT

tel: 020 7927 2376/2075 fax: 020 7637 2853 website: www.cesar-trial.org



ISRCTN47279827

Conventional Ventilation or
ECMO for
Severe
Adult
Respiratory Failure

address

date

Dear [patient name]

You may recall that I wrote to you recently regarding the follow-up at 6 months for the CESAR study. I have not yet received a reply from you and I appreciate that you may not wish to think about this at the present time. However, the follow-up is a very important part of the study and information obtained from it will help us to determine which treatment is better.

This assessment is being carried out as patients and researchers feel strongly that it is very important not just to look at the short-term, but also to compare the longer-term health of people who had conventional treatment with those who had ECMO. I am therefore writing to ask if you are prepared to have a follow-up visit and also to ask for your permission to obtain information about your health from your GP records.

It is possible that we will be funded to conduct additional, longer term follow-up assessments. So that we do not lose contact with you we are asking for your agreement to send your name to an organisation called the NHS Central Register (based at the General Register Office) that holds the name of the area where you are registered with a GP. This will help us to keep in contact with you in the future. If you agree, you will not need to do anything except to tick the appropriate box on the enclosed reply slip.

I would be very grateful if you could complete the enclosed reply slip and return it to me in the freepost envelope as soon as possible.

If you have any queries about CESAR or the NHS Central Register please do not hesitate to contact me.

Yours sincerely

Steven Robertson

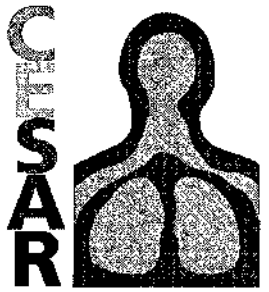
Data Management Co-ordinator

steve.robertson@lshtm.ac.uk

Enc: reply slip

freepost envelope

Conventional Ventilation or
ECMO for
Severe
Adult
Respiratory Failure



Agreement to participation in follow-up and access to information from your GP and the Central Register

Please complete and return this reply slip in the freepost envelope provided

Name:	**GP's name:**
Address: (including postcode)	**GP's Address:** (including postcode)
Tel. number:	**GP's tel. number:**
NHS number: (if known)	

Please amend or add to these details if they are wrong or incomplete

(Please tick appropriate box)	Yes	No
I agree to be visited at home	☐	☐
I do not wish to be assessed at home but agree to the following:		
• A telephone interview	☐	☐
• A postal questionnaire	☐	☐
I agree to information being obtained from my GP records	☐	☐
I agree for CESAR to request details from the NHS Central Register in order to keep in touch with me at a later date and to follow-up my health status.	☐	☐
I would like to receive annual updates about the study	☐	☐
I would like to be asked at the end of the study whether I wish to see the results	☐	☐

If you have agreed to any part of the follow-up please let us know how you would like us to contact you to make arrangements in the future (please tick as appropriate):

Post ☐

Telephone ☐

Email (please provide address) _____ ☐

Signature:_____ Date: ☐☐ ☐☐ ☐☐☐☐ dd/mm/y

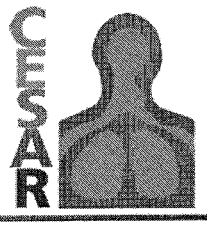
Confirmation letter for patient 6-month follow-up

CESAR General Practice Advisory Group

Department of General Practice and Primary Health Care

University of Leicester

Leicester General Hospital



ISRCTN47279827

[Patient's address]

[date]

Dear [patient name]

Re: 6-month follow up

Thank you for telephoning me to discuss your CESAR follow-up visit. Thank you for agreeing to this assessment. This is being carried out as patients and researchers feel strongly that it is very important not just to look at the short-term, but also to compare the longer-term health of people who had conventional treatment with those who had ECMO.

The assessment will include questions about your general health and quality of life, a 'blowing test' to examine your lung function, and an examination of your arm movements. It is important that I do not know which treatment you received when you were in hospital. Some treatments can leave scars in the neck, and so I would like you to wear the enclosed neck scarf for the duration of the assessment when we meet.

There will also be some questions about any costs incurred by you and your family as a result of your health care since discharge. You may find it useful to refer to the Events Diary that we sent to you after discharge when answering these questions. The whole assessment will take approximately 1 hour.

I enclose two questionnaires for you to complete beforehand which I will collect at my visit. If you have any difficulties completing these we can go through them when I arrive.

I confirm that the date and time of the visit is [e.g. Tuesday 12th June 2002] at ** : ** 24 hours. Please do not hesitate to call me if you need to change this.

Yours sincerely

[research assistant's name]

CESAR Trial Research Assistant

Tel: 0116 258 4367

Fax: 0116 258 4982

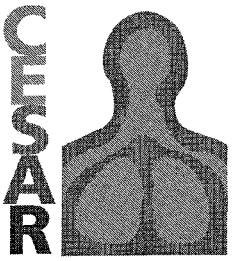
email

Enc: Quality of Life Questionnaire

St George's Hospital Respiratory Questionnaire

CESAR neck scarf (to be worn during assessment)

Conventional Ventilation or
ECMO for
Severe
Adult
Respiratory Failure



INFORMATION ABOUT CESAR

[patient's name] was enrolled in the CESAR study when he/she was in intensive care with serious breathing problems. Further information about CESAR is set out below.

What is the study trying to find out?

This study is comparing two ways of looking after patients with serious breathing problems. One way uses a ventilator to push oxygen into the lungs. We call this conventional ventilation as it is the most common method. The other way uses a system called ECMO to by-pass the lungs. This is only available in one place (Leicester), and only available for this study. At this time, we do not know if conventional ventilation is better or worse than ECMO for patients with serious breathing problems. This study is designed to help decide the best way of caring for patients with these problems so that more patients survive. It involves the co-operation of many doctors and nurses in hospitals throughout the UK.

What is already known about treatments for patients with severe breathing problems?

Conventional ventilation

One advantage of staying on this method is that there is usually no need to move very ill patients out of their local intensive care unit. This form of care is currently considered the best standard care, and has been used for many years. This means that the staff are very experienced in using it. However, using a ventilator to give oxygen at high pressure over a long period of time causes some lung damage to patients who already have breathing problems.

ECMO (extra-corporeal membrane oxygenation)

ECMO involves an operation (under anaesthetic) to set up a temporary by-pass for the patient's lungs. While on ECMO, patients stay on very gentle ventilation which may

help the lungs recover. Glenfield Hospital in Leicester is the only UK hospital with a reasonable length of experience in using ECMO for adults, so patients may have to be transferred some distance. Transferring very ill patients may be risky, but despite this ECMO may well be helpful. The early results of using ECMO appear promising. However, we are not yet sure whether ECMO is better or worse than conventional ventilation. So while it is being investigated, ECMO is only available in this study.

What does being in the study involve?

- Half the patients in the study will continue to be treated on a ventilator.
- The other half will be transferred to Glenfield Hospital, Leicester to be considered for ECMO.

Once in the study, the patient's treatment is decided by chance, rather like the toss of a coin. This element of chance is important so that the two methods can be tested fairly. The doctor calls a central office and is told which of the two treatments will be given. If the patient is assigned to have ECMO, then transfer to Leicester will be required. An experienced transport team comes from the ECMO Unit to transfer the patient. The quickest and safest type of transport will be arranged. This is usually either an ambulance or a helicopter.

We send written information to patients when they are discharged home.

CESAR Data Co-ordinating Centre

Medical Statistics Unit

London School of Hygiene and Tropical Medicine

Keppel Street

London WC1E 7HT

Tel: 020 7927 2376/2075

Fax: 020 7637 2853

Website: www . c e s a r- t r i a l . o r g

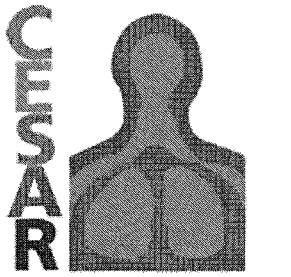
Letter to carer

CESAR General Practice Advisory Group

Department of General Practice and Primary Health Care

University of Leicester

Leicester General Hospital



ISRCTN47279827

Name

Address

Date

Dear [carer's name]

[patient's name] is enrolled in the CESAR study which aims to compare a new technique (extra-corporeal membrane oxygenation, known as ECMO) with usual treatment in patients with severe respiratory failure. The study includes a follow-up visit 6 months after the start of treatment. This assessment is conducted by a researcher at the patient's home.

The follow-up is being carried out as patients and researchers feel strongly that it is very important not just to look at the short-term, but also to compare the longer-term health of people who had conventional treatment with those who had ECMO.

When [patient's name] was assessed at home 6 months after joining the study he/she named you as his/her carer. We are interested in the impact the care you are providing is having on you, and so would be very grateful if you could complete the enclosed questionnaire and return it in the freepost envelope provided. The information you provide will be treated with the strictest confidence and will not be made available to the person you care for.

I enclose for your interest a short description of the study. Many thanks for your help.

Yours sincerely

[research assistant's name]

CESAR Study Research Assistant

Tel: 0116 258 4367

Fax: 0116 258 4982

email

Enc: Caregiver Strain Index (CSI) questionnaire

Freepost envelope

Information about CESAR

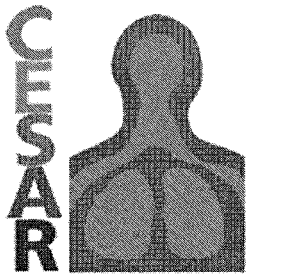
Reminder letter to carer

CESAR General Practice Advisory Group

Department of General Practice and Primary Health Care

University of Leicester

Leicester General Hospital



ISRCTN47279827

Name

Address

Date

Dear [carer's name]

You may remember a few weeks ago we asked for your help in completing a short questionnaire on your role as carer.

We have not yet received a reply, and would be very grateful if you could find the time to complete the questionnaire. A further copy is also enclosed.

We think it is very important to assess the impact of treatments on carers, and hope you will be able to help us in this way.

Yours sincerely

[research assistant's name]

CESAR Study Research Assistant

Tel: 0116 258 4367

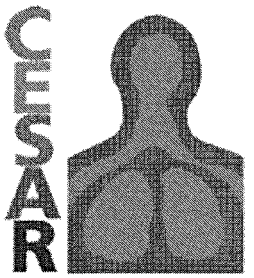
Fax: 0116 258 4982

email

Enc: Caregivers Strain Index (CSI) questionnaire

Freepost envelope

Requesting 6-month follow-up appointment confirmation letter



CESAR General Practice Advisory Group

Department of General Practice and Primary Health Care

University of Leicester

Leicester General Hospital

ISRCTN47279827

[Patient's address]

[date]

Dear [patient name]

Re: 6-month follow up

Thank you for agreeing to this assessment. This is being carried out as patients and researchers feel strongly that it is very important not just to look at the short-term, but also to compare the longer-term health of people who had conventional treatment with those who had ECMO.

The assessment will include questions about your general health and quality of life, a 'blowing test' to examine your lung function, and an examination of your arm movements. It is important that I do not know which treatment you received when you were in hospital. Some treatments can leave scars in the neck, and so I would like you to wear the enclosed neck scarf for the duration of the assessment when we meet.

There will also be some questions about any costs incurred by you and your family as a result of your health care since discharge. You may find it useful to refer to the Events Diary that we sent to you after discharge when answering these questions. The whole assessment will take approximately 1 hour.

The proposed date and time of the visit is [e.g. Tuesday 12th June 2002] at ** : ** 24 hours. Please contact me on the telephone number below to confirm this suits you, or to rearrange the visit if the proposed date and time is not convenient. When we have arranged a convenient time I will send an appointment confirmation letter to you with further details about the visit.

Yours sincerely

[research assistant's name]

CESAR Trial Research Assistant

Tel: 0116 258 4367

Fax: 0116 258 4982
email

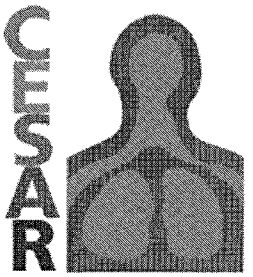
Researcher GP fax 1

CESAR General Practice Advisory Group

Department of General Practice and Primary Health Care

University of Leicester

Leicester General Hospital



ISRCTN47279827

Conventional Ventilation or ECMO for Severe Adult Respiratory Failure

FACSIMILE COVER SHEET

Date:

To: [patient's GP]

From:

Fax Number: [GP's fax number]

Subject: [patient's name, DoB and CESAR study number]

.....

Dear Dr ----------

As you may remember, the above patient is enrolled in the CESAR trial which aims to compare extra-corporeal membrane oxygenation (ECMO) with conventional treatment in severe respiratory failure. The trial includes follow up at 6 months post-randomisation with an assessment conducted by a researcher at the patient's home. [patient's name] is due to be assessed very soon. I have the following details for [patient's name]:

[address and telephone number]

I will be ringing the surgery in the next couple of days to check these are correct and that [patient's name] is still registered with you.

I would also be grateful if you could let me know of any reason you think it might be inappropriate to contact [patient's name] regarding the follow-up assessment, and whether there is any contraindication for spirometry (as listed below).

The patient has consented to the CESAR study obtaining information from GP records and a signed copy is held at the CESAR office. Thank you in advance for your help.

Sincerely

[researcher's name]

CONTRAINDICATIONS FOR SPIROMETRY

- Angina
- MI in last 6 weeks
- Poorly controlled hypertension
- Aortic aneurysm
- Surgery in last 6 weeks

FACSIMILE COVER SHEET

CESAR General Practice Advisory Group

Department of General Practice and Primary Health Care

University of Leicester

Leicester General Hospital

ISRCTN47279827

Date:

To: [patient's GP]

From:

Fax Number: [GP's fax number]

Subject: [patient's name, DoB and CESAR study number]

.....

Dear Dr ---------

As you may remember, the above patient is enrolled in the CESAR trial which aims to compare extra-corporeal membrane oxygenation (ECMO) with conventional treatment in severe respiratory failure. The trial includes follow up at 6 months post-randomisation with an assessment conducted by a researcher at the patient's home. [patient's name] is due to be assessed very soon. I have the following details for [patient's name]:

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Sincerely

[researcher's name]

CONTRAINDICATIONS FOR SPIROMETRY

- Angina
- MI in last 6 weeks
- Poorly controlled hypertension
- Aortic aneurysm
- Surgery in last 6 weeks