What if there is a problem?

If you have a concern or questions about any aspect of this study you should speak to your local study team who will do their best to answer your questions or you can contact the Patient Advice and Liaison Service (PALS); contact details can be found on the back of this leaflet

If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from your hospital.

In the event that something does go wrong and you are harmed during the study there are no special compensation arrangements. If you are harmed and this is due to someone's negligence then you may have grounds for legal action for compensation but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Will my taking part be kept confidential?

All information we collect about you will be kept in the strictest confidence. Only persons involved in the conduct or regulation of the study will have access to your personal details. We will also register your NHS number with the Health and Social Care Information Centre to help us follow up your health status. We will have confidentiality and security arrangements in place to ensure your details are dealt with in the strictest confidence. These details will be kept securely, with access restricted. You will not be named or otherwise identified in any study publication.

We will let your GP know that you are taking part in the study.

The ASAP trial is funded by the National Institute for Health Research (NIHR)

QUESTIONS OR CONCERNS?

If you would like more information, or have any concerns about the study please contact your local research team:

Local research team and PALS contact details to be inserted here:

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. This study has been reviewed by the South Central—Oxford C Research Ethics Committee.

NOTTINGHAM CLINICAL TRIALS UNIT

ASAP Patient Information Leaflet version 2.0 11-Feb-2014

ASAP

ADJUVANT STEROIDS IN ADULTS WITH PANDEMIC INFLUENZA

Patient Information Leaflet

Admitted to hospital with flu?

Information about the ASAP study

Admitted to hospital with flu?

We would like to invite you to take part in our research study.

ASAP ADJUVANT STEROIDS IN ADULTS WITH PANDEMIC INFLUENZA

What is the purpose of the study?

Some studies have shown that a steroid drug called dexamethasone improves the outcome in patients with pneumonia or severe 'blood poisoning'. There is uncertainty whether this drug might also improve the recovery of patients with severe flu infection. In this study we are trying to find out whether dexamethasone given for 5 days in addition to the normal treatment for flu is beneficial in patients admitted to hospital with flu during a pandemic.

We are asking up to 2200 patients admitted to hospital with a flu-like illness to take part.

What will I have to do?

If you decide to take part in the study you will be given some study medicine to take once a day for 5 days.

The study medicine will contain either:

1) dexamethasone or
2) a placebo (a dummy treatment which looks like the real medicine but contains no active ingredient.)

Using a placebo helps us make a fair comparison of the treatments. Neither you nor any of the doctors or nurses looking after you will know which treatment you are receiving (although if they need to find out they can do so). The decision about which treatment you receive will be decided by chance (rather like tossing a coin) and neither you nor your doctor will be able to choose. This is important as it ensures a fair comparison between treatments.

At the end of the study, we will be able to compare if patients who took dexamethasone did better compared to patients who took placebo.

In all instances, you will still receive the standard treatment currently used to treat patients with a flu-like illness.

About the study medicine

The study medicine is a liquid. You will be given a bottle containing enough medicine to last for 5 days. You will need to take 15ml by mouth once a day for 5 days. If you are too poorly to take your standard treatment by mouth, doctors may use a feeding tube to give you treatment directly to your stomach. If this happens, the feeding tube will also be used to give the study medicine.

Your doctor will explain how to take your medicine and you need to do this for 5 days. If you leave hospital then you will take the medicine home to continue it at home. You should continue to take your medicine as your doctor tells you to.

What information is collected?

We want to look in your medical notes for information about your illness and the treatment your doctor gives you whilst in hospital. Your doctor will give this to us with your permission.

We would like to find out how you are doing one month after you leave hospital. We will send you a short questionnaire; this will take about 5 minutes to complete. The questionnaire will be posted to you at your home, with a freepost return envelope. Your contact details will be collected and sent to the Coordinating Centre in Nottingham for this purpose. If we do not hear from you after a time, we will attempt to contact you by telephone to find out if you have received the questionnaire and how you are doing.

Possible disadvantages/risks

Steroids are very commonly used drugs. Side effects can include increased appetite, acne, mood changes such as becoming very aggressive, irritable and short tempered with people and rapid mood swings, such as feeling very happy one minute and sad and weepy the next. These are very rare. Scientific studies (trials) of steroids in pneumonia and blood poisoning have shown improved outcomes with steroids (patients less likely to die and reduced length of hospital stay) without any associated major harmful effects. Less reliable studies conducted during the 2009 pandemic have shown mixed results—in some studies patients who received steroids were more likely to die and in other studies patients were no more likely to die, compared to patients who did not receive steroids.

Possible benefits

We cannot promise that the study will help you, but the information that we get from the study might help improve the treatment of patients with pandemic flu in the future.

What happens after the study?

When you have finished your study medicine you will receive normal care whilst in hospital. If you have left hospital at this point you will not have to do anything. We will contact you with a questionnaire one month after you leave hospital.

Results of the study

The results of the study will be available after it has finished and will usually be published in a scientific journal and be presented at a scientific conference. However, you will not be identified in any report or publication. A summary of the results will also be sent to you.

What if there is a problem?

If you have a concern or questions about any aspect of this study you should speak to the local study team who will do their best to answer your questions or you can contact the Patient Advice & Liaison Service (PALS); contact details are on the back of this leaflet.

If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from your hospital.

In the event that something does go wrong and your partner/friend/relative is harmed during the study there are no special compensation arrangements. If your partner/relative/friend is harmed and this is due to someone's negligence then you may have grounds for legal action for compensation but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Will my partner/friend/relative's taking part be kept confidential?

All information we collect about your partner/relative/friend will be kept in the strictest confidence. Only persons involved in the conduct or regulation of the study will have access to your partner/relative/friend's personal details. We will also register their NHS number with the Health and Social Care Information Centre to help us follow up their health status. We would also like to collect your contact detail in case we need to contact you to find out how they are once they have left hospital. We will have confidentiality and security arrangements in place to ensure all details are dealt with in the strictest confidence. These details will be kept securely, with access restricted. Your partner/relative/friend will not be named or otherwise identified in any study publication.

We will let your partner/relative/friend's GP know that they are taking part in the study.

The ASAP trial is funded by the National Institute for Health Research (NIHR)

QUESTIONS OR CONCERNS?

If you would like more information, or have any concerns about the study please contact your local research team:

Local research team and PALS contact details to be inserted here:

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NOTTINGHAM CLINICAL TRIALS UNIT

ASAP PLR Information Leaflet version 2.0 11-Feb-14

ASAP

ADJUVANT STEROIDS IN ADULTS WITH PANDEMIC INFLUENZA

*Personal Legal Representative**

Information Leaflet

* may be a partner, friend or relative

Admitted to hospital with flu?

Information about the ASAP study

Admitted to hospital with flu?

We would like to invite your partner/*relative/friend* to take part in our research study.

ASAP ADJUVANT STEROIDS IN ADULTS WITH PANDEMIC INFLUENZA

What is the purpose of the study?

Some studies have shown that a steroid drug called dexamethasone improves the outcome in patients with pneumonia or severe 'blood poisoning'. There is uncertainty whether this drug might also improve the recovery of patients with severe flu infection. In this study we want to find out whether dexamethasone given for 5 days in addition to the normal treatment for flu is beneficial in patients admitted to hospital with flu during a pandemic.

We are asking up to 2200 p**atients** a**dmitted** to hospital with a flu-like illness to take part.

What will my partner/relative/friend have to do?

If you agree for your partner/friend/relative to take part in the study they will be given some study medicine to take once a day for 5 days.

The study medication will contain either:

1) dexamethasone or
2) a placebo (a dummy treatment which looks like the real medicine but contains no active ingredient.)

Using a placebo helps us make a fair comparison of the treatments. Neither you, your partner/ relative/friend, nor any of the doctors or nurses looking after them will know which treatment they are receiving (although if they need to find out they can do so). The decision about which treatment they receive will be decided by chance (rather like tossing a coin) and neither you, your partner/relative/friend or their doctor will be able to choose. This is important as it ensures a fair comparison between treatments. At the end of the study, we will be able to compare if patients who took dexamethasone did better compared to patients who took placebo.

In all instances, your partner/re**lative**/**friend will still** receive the standard treatment currently used to **treat patients with a flu**-like illness.

About the study medicine

The study medicine is a liquid. They will be given a bottle containing enough medicine to last for 5 days. Your partner/relative/friend will need to take 15ml by mouth once a day for 5 days. If they are too poorly to take their standard treatment by mouth, doctors may use a feeding tube to give them treatment directly to their stomach. If this happens, the feeding tube will also be used to give the study medicine.

If your partner/friend/relative stays in hospital less than 5 days then they will take the medicine home to continue it at home. They should continue to take the medicine as their doctor tells them to.

What information is collected?

We want to look in your partner/relative/friend's medical notes for information about their illness and the treatment their doctor gives them whilst in hospital. Their doctor will give this to us with your permission.

We would like to find out how your partner/relative/ friend is doing one month after they leave hospital. We will send them a short questionnaire; this will take about 5 minutes to complete. The questionnaire will be posted to your partner/relative/friend at their home, with a freepost return envelope. Their/Your contact details will be sent to the Coordinating Centre in Nottingham for this purpose. If we do not hear from them after a time, we will attempt to contact them by telephone to find out if they have received the questionnaire and how they are doing.

Possible disadvantages/risks

Steroids are very commonly used drugs. Side effects can include increased appetite, acne, mood changes such as becoming very aggressive, irritable and short tempered with people and rapid mood swings, such as feeling very happy one minute and then very sad and weepy the next. These are very rare. Scientific studies (trials) of steroids in pneumonia and blood poisoning have shown improved outcomes with steroids (patients less likely to die and reduced length of hospital stay) without any associated major harmful effects. Less reliable studies conducted during the 2009 pandemic have shown mixed results—in some studies patients who received steroids were more likely to die and in other studies patients were no more likely to die, compared to patients who did not receive steroids.

Possible benefits

We cannot promise that the study will help your partner/friend/relative, but the information we get from the study might help improve the treatment of patients with pandemic flu in the future.

What happens after the study?

When your partner/friend/relative has finished their study medicine they will receive normal care whilst in hospital. If they have left hospital at this point they will not have to do anything. We will contact them with a questionnaire one month after they leave hospital.

Results of the study

The results of the study will be available after it has finished and will usually be published in a scientific journal and be presented at a scientific conference. However, your partner/relative/friend will not be identified in any report or publication. A summary of the results will also be sent to your partner/relative/friend.