calories

Patient Information Sheet

CALORIES: Clinical and cost-effectiveness of early nutritional support in critically ill patients via the parenteral versus the enteral route

Introduction

We would like to invite you to take part in a research study which aims to find out the best way of providing early nutrition to patients in critical care. The study is being conducted in National Health Service (NHS) critical care units around the UK, and is being managed by the Intensive Care National Audit & Research Centre (ICNARC) in London.

Before you decide, it is important that you understand why the research is being done and what it involves. **One of our team will go through this information sheet with you and answer any questions you may have.** Feel free to talk to your friends and family about the study if you wish and please ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

During illness, after surgery or following an injury, good nutrition is essential to help repair damaged tissues and aid recovery. However, providing nutrition to patients, especially those in the critical care unit, is difficult because they are often unable to eat food normally. Patients who are unable to eat adequate amounts of food are fed special liquid diets which contain all the essential nutrients they need (e.g. energy, vitamins and minerals). Liquid diets may be given either via a small tube that is passed into the stomach via the nose or mouth (enteral or tube feeding) or via a catheter into a vein, directly into the bloodstream (parenteral or intravenous feeding).

Both tube feeding and intravenous feeding are routinely used to feed patients in critical care units but it is not known which is the best method for providing nutrition, particularly during the first few

days following admission, when patients are often at their sickest. The Department of Health is supporting this clinical study in order to answer this important question.

Why have I been asked to take part in the study?

You have been asked to take part in the study because the doctors think that you are likely to remain in the critical care unit for at least three days, and will be unable to eat and drink normally during that time. To meet your nutritional needs, you will need either tube feeding or intravenous feeding.

Do I have to take part?

Joining the study is entirely voluntary. Once you have read this information sheet and you agree to take part, we will ask you to sign a consent form. You are free to withdraw from the study at any time, without giving a reason, and this will not affect the standard of care you receive.

What will happen to me if I take part?

To find out which of the two methods (tube feeding or intravenous feeding) is best, we will put each patient who agrees to take part into either the tube feeding group or into the intravenous feeding group. At the end of the study we will compare the results to see which method of feeding is best.

To make sure the groups are the same, each patient will be put into one of the two groups randomly. This will be done by computer based on chance (as if it were tossing a coin). There is an equal chance that you will receive tube feeding or intravenous feeding. Neither you nor your doctor will be able to decide which method of feeding you receive.

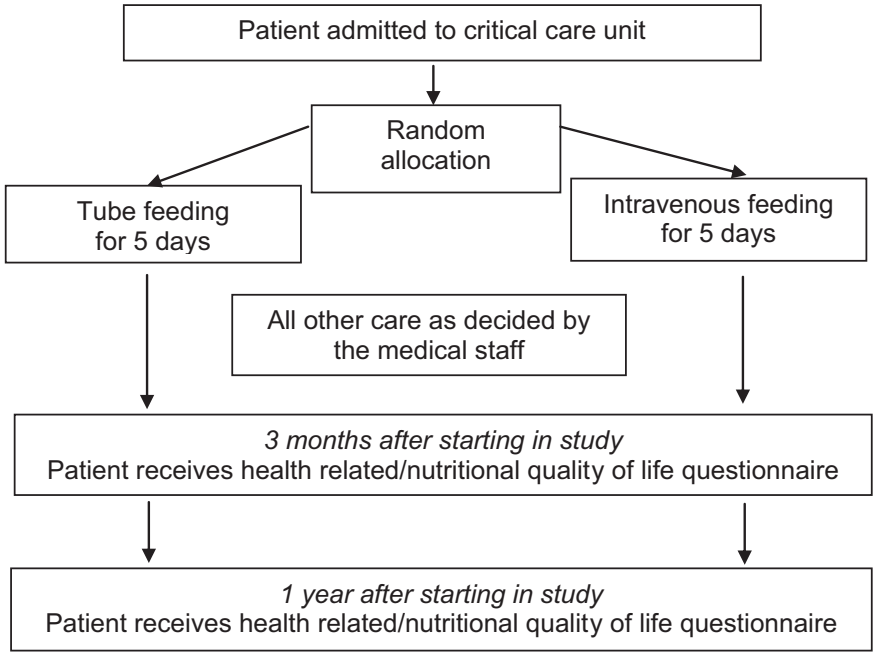
If you are assigned to the tube feeding group, the amount of liquid feed required will be calculated based on your body weight and nutritional needs, and administered according to standard procedures routinely used in your hospital's critical care unit. The liquid feed will be given via a soft, narrow feeding tube inserted into the stomach via the nose or mouth. These tubes are routinely placed into patients admitted to the critical care unit, not only for the purpose of feeding, but also for giving medication and to help reduce the risk of abdominal bloating and vomiting. You will receive tube feeding for five days, unless you are able to eat normally before then. After this, the medical team looking after you will decide whether to continue tube feeding or not, based on your nutritional needs. You will receive all other care as usual.

If you are assigned to the intravenous feeding group, the amount of liquid feed required will be calculated based on your body weight and nutritional needs, and administered according to standard procedures routinely used in your hospital's critical care unit. The liquid feed will be given via a catheter that is placed into a large vein, usually in the neck or chest called a central venous

catheter. Most patients admitted to a critical care unit will have a central venous catheter inserted for administration of intravenous fluids and medication, as well as for intravenous feeding. You will receive intravenous feeding for five days, unless you are able to eat normally before then. After this, the medical team looking after you will decide whether to continue intravenous feeding or not, based on your nutritional needs. You will receive all other care as usual.

We will collect information about your progress during your stay in the critical care unit and in hospital. You will be contacted by a researcher from ICNARC by letter three months and then one year after you started in the study, and asked to fill in a short questionnaire about your general health and wellbeing. We will need your home address for this. The questionnaires will take about 15-20 minutes to complete. Please see patient progress diagram below.

Patient progress



Other than the way in which you are fed (either tube feeding or intravenous feeding) taking part in the study will not affect the care you receive, which will be decided by the medical team looking after you. At any time during the study the medical team responsible for your care may decide to change the way you are fed depending on what is appropriate for your needs at the time.

Your GP will be informed about your participation in this study. A researcher from ICNARC will contact your GP before sending you the questionnaires to complete about your general health and well being at three months and again at one year after you entered the study.

What are the possible disadvantages and risks of taking part?

Both tube feeding and intravenous feeding are routinely used in the critical care unit to feed patients who are unable to eat a normal diet. Tube feeding is more common but we do not know if it is better than intravenous feeding. There are no additional risks to you if you agree to participate in the study, the risks associated with both methods of feeding would be present regardless of taking part in this study.

Tube feeding

The risks are mainly related to placement of the feeding tube and may include irritation to the nose, nose bleeds, sinusitis or, rarely, the feeding tube entering the lung.

Intravenous feeding

The risks are mainly related to placement of the central venous catheter and may include injury to the blood vessel causing bleeding or bruising, infection or very rarely puncture of the lung.

Most patients admitted to a critical care unit will have both a feeding tube and a central venous catheter inserted as part of routine care. You will be monitored very closely for any complications while you are receiving either tube feeding or intravenous feeding and during your entire stay in the hospital.

What are the possible benefits of taking part?

We cannot promise that participation in the study will benefit you during your hospital stay but the information we get from this study may help improve the way in which we feed patients in critical care units in the future.

What happens when the research study stops?

Once the research has finished you will receive usual medical care up to and following discharge from hospital. However, three months and then one year after you started in the study you will be contacted by a researcher from ICNARC by letter to ask you to answer some questions about your general health and wellbeing.

What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. If you wish to complain about any aspect of the way you have been approached or treated during the course of this study, please contact the Consultant leading the study at your hospital (name and contact details are provided below) or the Hospital's Patient Advice & Liaison Service (PALS) – details provided below.

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against [add relevant NHS Trust here] but you may have to pay your legal costs. The normal NHS complaints mechanisms will still be available to you (if appropriate).

Will my taking part in this study be kept confidential?

Yes at all times, we will follow ethical and legal practice and all information about you will be handled in strict confidence. Authorised members of the research team at your hospital will need to have access to your medical records in order to collect information needed for this study.

Where possible, any information about you which leaves the hospital will have your name and address removed so that you cannot be recognised from it. As some patients may lose touch with their hospital, we will need to collect important basic information from national records held by the NHS Data Linkage Service. To ensure that we identify you correctly on the Data Linkage Service database, your name, date of birth, postcode and NHS number will be given to ICNARC for this purpose. In addition, ICNARC will also be given your address and telephone number so that the questionnaires (mentioned previously) can be sent to you. This information will be stored securely and in strict confidence at ICNARC. Procedures for handling, processing, storing and destroying data at [add relevant NHS Trust here] and at ICNARC are compliant with the Data Protection Act 1998.

What will happen if I don't want to carry on with the study?

You may withdraw from the study at any time but we would like to use the data collected up to your withdrawal.

What will happen to the results of the research study?

The results of the study will be published in a scientific journal and on the ICNARC website (www.icnarc.org). It will not be possible to identify any individual who has taken part in the study in the report. If you would like a copy of the published results, please contact the Consultant leading the CALORIES Study at your hospital (contact details below).

Who is funding and organising the study?

This study is being funded by the National Institute for Health Research (NIHR), Health Technology Assessment (HTA) Programme. The study is being sponsored and managed by the Intensive Care National Audit & Research Centre (ICNARC).

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 interests. This study has been reviewed and given a favourable opinion by the North West London Research Ethics Committee 1.

Thank you for taking the time to read this information

For more information about CALORIES:

Consultant leading the CALORIES Study in your hospital:

[Insert name local Principal Investigator]

[Contact telephone number local Principal Investigator]

Research Nurse:

[Insert name of nurse working on CALORIES locally]

[Contact telephone number of nurse]

If you are unhappy with any aspect of the study:

If you do not wish to speak to the research staff listed above, please contact:

Patient Advisory and Liaison Service (PALS):

[insert local PALS contact details here]