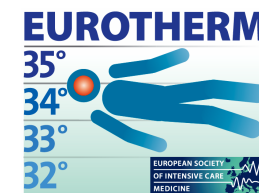


Further information and contact details

Site Specific

Name, address, telephone and fax numbers, email address



PATIENT INFORMATION SHEET

A study examining the effects of cooling the body after severe brain injury

Short Title Eurotherm3235trial

Introduction

While you were in intensive care a relative agreed to let you take part in this research study. Now that you are recovering from your illness you are being invited to continue in this study. To help you decide if you want to continue, you need to understand why the research is being done and what it will involve. Please take time to read the following information as it will explain the risks and possible benefits of continuing to take part. Talk to others about the study if you wish.

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 would like to continue to take part.

Part 1 tells you the purpose of the study

Part 2 tells you about the conduct of the study

Part 1

What is the purpose of the study?

You were treated in the Intensive Care Unit following a severe brain injury. After a brain injury, the brain can swell inside the skull like a bruise. If the brain swells, it can lead to a build up of pressure which can further damage parts of the brain.

Cooling the body down to between 32-35 °C within 72 hours after brain injury, may or may not help to reduce brain swelling and prevent further brain damage. We are not sure whether this treatment makes a difference to how well people recover in the longer term.

This study will find out how well people with brain injury have recovered 6 months after the injury. The study will compare the effect of two treatments:

1. The usual care given to people who have had a severe brain injury
2. The usual care with the added treatment of cooling the body to between 32-35°C for at least 48 hours.

Why have I been chosen?

You were chosen because you had suffered a severe brain injury with brain swelling and you needed intensive care. Your relative agreed for you take part in the study. We gave you one of the two treatments. We would now like to be able to find out how you are recovering 6 months after your injury.

Do I have to take Part?

No. It is up to you to decide. We will explain the study and go through this information sheet with you. If you do decide to continue, you will be given this sheet to keep and will be asked to sign a consent form. You are still free to withdraw at any time, without giving a reason. This will not affect the standard of care you receive.

however have to pay your legal costs. The normal *hospital trust* complaints mechanisms will still be available to you (if appropriate).

Will my taking part in this study be kept confidential?

All information which is collected about you during the course of this research will be kept strictly confidential. Study information will be held on a computer, but we will ensure that all appropriate safeguards are put in place to keep the information secure. Any information that leaves the hospital where you were treated will have your name and address removed so that you cannot be recognised.

Permission was given by your relative to inform your family doctor that you are taking part in the study.

What will happen to the results of the research study?

All information collected as part of this study will be treated as confidential. Individuals will not be identified in any study reports.

Who has reviewed the study?

All research in *hospital trust/NHS* is assessed by an independent group of people, called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. This study has been approved by Research Ethics Committees in **Scotland and England**. The study has also received hospital management approval.

Thank you for taking the time to read this information leaflet.

Part 2

What if new information becomes available?

Sometimes we get new information about the treatment being studied. If this happens, the study nurse/doctor will tell you and will discuss whether you would like to continue to be in the study. If you decide to withdraw at this time, your care will not be affected. If you decide to continue in the study, you may be asked to sign another consent form at that time.

If the study is stopped for any other reason, we will tell you and your normal care will not be affected.

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

If you decide that you don't want to carry on in the study, you will be asked to complete a study withdrawal form and your care will not be affected.

We will use the data collected up to your withdrawal but will stop collecting data from that point unless you tell us otherwise. You should make it clear on the withdrawal form, which part of the study you are withdrawing from.

What if there is a problem?

If you have a concern at any time about any aspect of this study, you should ask to speak to ***contact name and telephone number*** who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the ***hospital trust*** Complaints Procedure. Details can be obtained from the hospital where you were treated.

In the event that something unforeseen does go wrong and you are harmed during the research due to someone's negligence, you may have grounds for legal action for compensation against the sponsors of the study - NHS Lothian and The University of Edinburgh. You may

What will happen to me if I decide to take part?

If you decide to take part, we will ask you to sign a consent form. **You are now recovering from the injury so Part 1 of the trial is finished.**

Part 1

As we are not sure what the best treatment is, people who take part in this study are put into one of the two treatment groups. They either continue to receive normal care or receive this plus body cooling. To make sure the groups are the same to start with, each person has been put into a group by chance. This is like the toss of a coin and so there was a 50% chance of you receiving the cooling treatment.

You may or may not have been put into the cooling group. The research procedure for cooling the body takes place in two stages. During the first phase, an infusion of cold saline (salt water) is given to quickly lower the body temperature. During the second phase, cooling is continued using, for example, ice packs placed under the arms and legs or a cooling machine. This second phase of cooling continues for at least 48 hours and until the doctors are sure that the swelling in the brain has reduced. The body is then re-warmed slowly over 16-20 hours. **Both of these stages have already taken place in the intensive care unit.**

Part 2

This study is looking at the effect of these two different treatments on recovery 6 months after brain injury. If you agree to continue in the study, we will send you a questionnaire by post 6 months after the injury. This is to find out how well you have recovered. You can get help from your relative to fill in the questionnaire if you can't do it by yourself. If we do not receive a completed questionnaire from you, we may telephone your relative to complete the questionnaire over the telephone. We may also telephone your family doctor for information related to your taking part in this study.

What is the procedure that is being tested?

The procedure that is being tested is cooling the body down to between 32-35 °C.

Cooling the body is not a new procedure and has recently become a recommended treatment for people who have suffered a major heart attack (Cardiac Arrest). It has also been used occasionally to treat people with severe brain swelling but we are not certain whether or not this improves recovery.

Previous trials of cooling after brain injury have not included enough people to show whether or not this treatment is effective at improving recovery. This is the largest study of cooling after severe brain injury to date and 1800 people will take part from across the world.

What are the alternative treatments?

The alternative treatment for severe brain injury is the usual care given to patients in the intensive care unit.

What are the possible disadvantages and risks of taking part?

This study allows standard care to be given to everyone that takes part. No matter which group you were put into, you will have received normal care.

Everyone who suffers a severe brain injury is at risk of a number of complications such as pneumonia and other infections whether or not they are cooled.

Cooling the body down to between 32-35 °C can cause skin redness and can increase the chance of the skin breaking down. The nurses and doctors looking after you have checked your skin regularly and tried to minimise the risk of the skin breaking down.

There is also an increased risk of having an irregular heartbeat, low blood pressure and problems with blood clotting during cooling. There is also a risk of developing low blood pressure during re-warming. This is a reason why the body is re-warmed slowly (over 16-20 hours). These are known side effects of cooling and, the doctors and nurses in the intensive care unit are used to caring for people who are being cooled. There are guidelines in place for the treatment of people being cooled to minimise the risk of any side effects.

What are the possible benefits of taking part?

You may have been put into the cooling group and this treatment may have helped to reduce the swelling in the brain. We cannot say whether this study will help you but we hope that the treatments given have helped you.

The information we get from this study will help us to find out the best treatment for people with a severe brain injury in the future.