

THE GALA TRIAL

PATIENT INFORMATION BOOKLET

A RESEARCH STUDY COMPARING GENERAL ANAESTHETIC WITH LOCAL ANAESTHETIC FOR CAROTID ENDARTERECTOMY

YOUR SURGEON'S NAME IS:

THE CONTACT TELEPHONE NUMBER IS:

Invitation to take part in GALA

You are being invited to take part in a research study comparing local anaesthetic with general anaesthetic for carotid endarterectomy surgery. Before you decide whether to participate it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and to discuss it with others 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 wish to take part. Thank you for reading this.

Introduction to the study

Your surgeon has told you that you need an operation to remove some narrowing in one of the arteries in your neck. This is called a carotid endarterectomy. Your surgeon will also have explained that there is a small risk that the surgery may cause a stroke. However previous research has proved that this is much less than the risk of stroke without the operation.

We are now doing some further research to see if we can make carotid surgery even safer. In this study, half of the patients will have their operation under a general anaesthetic and half with local anaesthetic. Both types of anaesthetic are used routinely for carotid surgery but at the moment we do not know which one is best.

The main phase of the GALA Trial aims to recruit 5,000 patients. This includes 700 patients already recruited into the start-up phase.

What is general anaesthesia?

This is when you are given anaesthetic drugs into a vein in your arm (intravenous) or inhale anaesthetic gases through a face mask to make you unconscious during the surgery. You will wake up after surgery in the recovery area outside the operating theatre.

What is local anaesthesia?

Anaesthesia is provided by injection of local anaesthetic solution into the skin on your neck. This will numb the area (similar to techniques used at the dentist). You will be aware that the surgeon is doing the operation, but it should not be painful. Any discomfort will be relieved by further injection of local anaesthetic by the surgeon, or the use of intravenous pain killing drugs. Occasionally, if surgery is longer or more difficult than usual, or you become distressed, a general anaesthetic may be required to complete the surgery.

Risks of the two anaesthetic techniques

The risks of general anaesthesia include adverse reactions to anaesthetic drugs and complications from the tube put into your wind-pipe to help you breathe while you are unconscious.

The risks of local anaesthesia include adverse reactions to local anaesthetic drugs, damage to structures in the neck from needle injections, and if required, the risks of conversion to general anaesthetic.

The anaesthetist will discuss the anaesthetic techniques, and your own particular medical problems, with you before your operation.

What are the risks and benefits?

We do not know whether the operation will be safer with one type of anaesthetic rather than another. This is what we are trying to find out.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you should keep this information sheet. You will also be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. This will not affect the standard of care you receive.

What will happen if I decide to take part?

If you decide to take part, your operation will be carried out under either local or general anaesthetic.

So that the research is scientifically accurate neither you nor your surgeon can decide which type of anaesthetic you are given. Patients taking part in the trial will be put into equal sized groups of either general anaesthetic or local anaesthetic which are then compared. To make sure that there are equal numbers in each group, the type of anaesthetic to be used is selected randomly. This means that your anaesthetic will be chosen by chance, like tossing a coin. The GALA Trial is therefore called a 'Randomised Trial'. You will have an equal chance of being given local or general anaesthetic.

Apart from the anaesthetic there will be no difference in the operation that your surgeon will do. You will not need any extra tests.

About one month after your surgery you will be asked to attend a short, routine post-operative consultation with a physician here at the hospital.

If you are a patient living in the UK you will also be asked to complete a simple questionnaire about your general health. The questionnaire, including a reply paid envelope for returning it, will be sent direct to you by the Trial Office in Edinburgh.

A year after your operation date, ALL patients randomised into the Trial will be asked to complete a short questionnaire. You will not have to attend any further appointments in connection with the GALA Trial.

If you have a local anaesthetic it will be similar to the type a dentist might use to make your mouth go numb. When the anaesthetic is given you may feel some minor discomfort. However once it has taken effect you will not feel any pain although you will be awake during the operation. If you have a general anaesthetic you will be asleep during the operation which will also be painless.

What if something goes wrong?

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for this. If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms will be available to you.

Who will be told about my operation?

Only information necessary for the purposes of the trial will be collected from your medical records. Any information provided will be entirely confidential and only available to members of staff directly involved in running the GALA Trial together with your hospital doctors and the research staff working with them. Your family doctor will also be told that you are taking part.

When the results of the study are published it will not be possible to identify individual patients from the results.

Who is organising and funding the research?

The GALA Trial is organised by the Universities of Edinburgh, Leeds, Bath, Oxford and York. It is funded by The Health Foundation which is an independent UK healthcare charitable foundation. Funding has also been received from the European

Society for Vascular Surgery. The GALA Trial is a non-commercial trial.

What happens now?

We would like you to think very carefully about whether or not to join the study. It is entirely voluntary and if you decide not to join in it will not influence your care in any way. If you have strong feelings about the type of anaesthetic that you would prefer you do not have to take part in the study. If you agree to take part you will be asked to sign a consent form to show that you have read this booklet and understand what the study involves.

Once you have decided to take part you are still free to change your mind at any time. If you do, you will be given the type of anaesthetic which you prefer.

And finally...

If you think of other questions that you want to ask between now and coming into hospital for your operation you can telephone your surgeon's secretary who will arrange for you to speak to your surgeon. The name of your surgeon and contact telephone number are shown on the front page of this leaflet.

Thank you for reading this leaflet.

**Information is available on the GALA Trial website:
www.galatrial.com**