Patient Information Sheet [Detailed]

GOT-IT Trial: A pragmatic group sequential placebo controlled randomised trial to determine the effectiveness of Glyceryl trinitrate for retained placenta.

You have been asked to take part in our research study because your placenta is taking longer than usual to be delivered (retained placenta) and you may require a procedure in the operating theatre to help the placenta to deliver. Before you decide whether you wish to take part, 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 leaflet carefully. Ask us if there is anything that is not clear or if you would like more information. Please consider carefully whether or not you wish to take part.

What is the purpose of the study?
Eleven thousand women a year in the UK have a retained placenta. At the moment the standard treatment for this is a procedure called manual removal of the placenta which involves anaesthetic - either spinal or general. In this study we hope to prove that a drug called Glyceryl trinitrate (GTN) can be used to treat this problem without the need for surgery. GTN is a known drug and used in the treatment of angina. In order to do this we will give half the women in our study GTN and half a placebo (dummy drug - harmless and contains no treatment). No one will know which drug is given so that we can then compare the results fairly and see if this treatment works.

Do I have to take part?
No. It is up to you to decide whether or not you wish to take part. This will not affect your care in any way.

What will happen to me if I take part?

- You will be asked to sign a consent form and answer some questions about your medical history and current medications you are on.
- Your blood pressure, pulse and temperature will be taken and a small blood sample (about 10 mls, about two teaspoonsfuls) will be taken.
- You will need to have a venflon (tube in your hand for giving fluids during labour) put in before you undergo any procedures. This would be part of your normal care if you needed an operation.
- You will be given, at random, either GTN or placebo.
This will be given as a spray that you put under your tongue. You will be shown how to do this and only need to take it once (2 sprays under your tongue).

We will take your blood pressure, pulse and temperature after 5 minutes and then at 15 minutes.

If after 15 minutes you have still not delivered your placenta you will go to theatre as planned and have it removed manually.

Before you are discharged from hospital we will take another blood sample to check your iron levels (haemoglobin) and ask you to complete a questionnaire about your experience

Six weeks after you have had your baby we will ask you to complete another questionnaire about your experience and post this back to us in a stamped addressed envelope which will be provided.

What are the possible disadvantages and risks of taking part?

All medications can sometimes cause side effects. GTN is a drug widely used for the treatment of angina (a heart condition). It is a drug which relaxes your blood vessels and muscles to help with blood flow. Common side effects include headache, dizziness, flushing/feeling hot, a drop in your blood pressure and a rise in your heart rate (pulse). This drug does not stay in your body for very long so any side effects are often very short lived and you can be given painkillers if you have a headache.

What are the possible benefits of taking part?

The possible benefit in participating in this trial is that you may deliver your placenta without the need for an anaesthetic, transfer to the operating theatre and an operation.

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

You are free to withdraw from the study at any time without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care that you receive. If you withdraw we may still wish, with your permission, to use any anonymised data obtained as a result of your participation.

What if there is a problem?

Being in the trial does not affect your rights. If you have a concern about any aspect of this study, you should ask to speak with the clinical researchers who will do their best to answer your questions. It is unlikely that something will go wrong, but if 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 NHS Lothian but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

What happens when the study is finished?

When you have delivered your placenta, your medical and postnatal care will continue as normal. Anonymised information that we collect and that you provide as part of the research study will be kept securely for a minimum of 5 years at The University of Edinburgh.

Will my taking part in this study be kept confidential?

Yes. All information which is collected about you during the course of the research will be kept strictly confidential. You will be allocated a unique code and your responses to the questions will be held in a coded form in a secure central database which is only accessible to the research team. The data log linking your personal details (such as your name) to the research data will be destroyed at the end of the trial. Your responses will not be identified when the results of the study are published.

If you tell one of the research team something about your health that we are concerned about during the follow-up interview or in the questionnaire, then we might advise you to speak to a health professional or ask for your consent to make a referral for you.

If you tell us something about the care that you have received that we are concerned about, we will advise you on standard procedures for dealing with clinical malpractice.

With your consent we will inform your GP that you are taking part.

To ensure that the study is being run correctly, we will ask your consent for responsible representatives from the Sponsor (NHS Lothian and University of Edinburgh) to access your medical records and data collected during the study, where it is relevant to you taking part in this research. The Sponsor is responsible for overall management of the study and providing insurance and indemnity.

What will happen to the results of the current research study?

The results of this study will be published e.g. in medical journals, reports and textbooks. The anonymised data and may be considered for possible use in future ethically approved projects.

Who is organising and funding the research?

The research is taking place across the UK but is being led by Dr Fiona Denison (Consultant Obstetrician) who is based in Edinburgh. The study has been funded by The Health Technology Assessment Programme (HTA), which is part of the National Institute for Health Research (NIHR).

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee (REC). A favourable ethical opinion has been obtained from North East - Newcastle and North Tyneside 2 - REC. Medicines and Healthcare products Regulatory Agency (MHRA) and NHS management approval have also been obtained.