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Patient Information Sheet

HubBLE Trial – Haemorrhoidal Artery Ligation (HAL) versus Rubber Band Ligation (RBL) for haemorrhoids.

We would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to family, friends or health professionals 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 wish to take part.

What is the purpose of the study?

Haemorrhoids are swellings around the back passage which can cause bleeding, pain and itching and can protrude. When they become enlarged, surgery is often advised as it is an effective way to control the symptoms. This study will compare two treatments that are currently used in the UK, they have both been shown to improve patients' symptoms but we do not know which one is best. The two treatments are: Rubber Band Ligation and Haemorrhoidal Artery Ligation.

What is the Rubber Band Ligation treatment for haemorrhoids?

This is a procedure where a band is placed around the base of the haemorrhoid, and can be performed without anaesthetic [in the outpatient department] or [in theatre] ~~delete as applicable to account for local variation~~. However, a high recurrence rate (approximately 1 in 3 people need further treatment) often leads to repeated treatments and further surgery.

What is the Haemorrhoidal Artery Ligation treatment?

This is a newer method of treatment that uses a surgical instrument (a Doppler probe) to locate haemorrhoidal arteries so they can be tied off. This operation requires an anaesthetic, but it has a low recurrence rate (approximately 1 in 10 people need further treatment), and unlike other surgical procedures it allows a swift return to normal activity with minimal discomfort after the operation.

Why have I been invited?

We are running this research in a number of hospitals in the UK and we hope that 350 patients will take part in this study. You have been chosen as you have been told that you require treatment for your haemorrhoids in this hospital.

Do I have to take part?

No you do not; it is up to you to decide. We will describe the study and go through this information sheet, which you can keep. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive. You do not have to decide today, the research nurse will call you before your next appointment and we will ask you for a decision at your next clinic appointment.

What will I have to do?

Before the treatment we will ask you some questions about your general health and about the symptoms associated with your haemorrhoids, such as pain and incontinence. You will receive the treatment for the group that you have been assigned to, and you will be asked similar questions at several stages following the treatment.

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Before the treatment:

If you decide to take part in this research, when you come to your next clinic appointment you will be asked to sign a consent form and answer some questions about your general health and symptoms related to your haemorrhoids, such as pain and incontinence. You will be randomly put into one of two groups: one will receive the Rubber Band Ligation as treatment and the other group will receive Haemorrhoidal Arterial Ligation as treatment. This means that neither you nor the doctor will be able to decide which treatment you will receive. As we do not know which of these treatments is the best, you have an equal (50/50) chance of being in either group.

Receiving the treatment:

When we know which group you are in, the next part of the research will be receiving the treatment.

[If you are going to have Rubber Band Ligation, this will be done on the same day that you sign the consent form but if you are going to have Haemorrhoidal Arterial Ligation a further appointment will be made. The appointment may take up to 12 weeks and this will be the same whether you take part in the study or not.]

or

[We will make an appointment for either the Rubber Band Ligation procedure or the Haemorrhoidal Arterial Ligation and you will come back for the treatment. The appointment may take up to 12 weeks and this will be the same whether you take part in the study or not.]

Delete as applicable to account for local variation

After the treatment:

We would like to collect information from patients who take part for one year following treatment. In research, this is called ‘follow-up’ and is important so that we know about long term benefits or negative effects of any treatment. Follow-up will involve you answering a number of questions about your general health, haemorrhoidal symptoms, including pain and incontinence and any further treatment you have had since the treatment. We will post the questionnaires to you with a return envelope (or give them to you in the clinic) and then we will telephone you to ask the follow-up questions. We will contact you at the following times:

- 1) One day after your treatment - to complete a short questionnaire(1-2 minutes)
- 2) One week after your treatment - to complete a short questionnaire (2-3 minutes)
- 3) Three weeks after your treatment - to complete a short questionnaire (2-3 minutes)
- 4) Six weeks after your treatment - attend a clinic appointment with the doctor where they will review your treatment; this would be the normal procedure following both treatments whether you take part in the research or not. You will be asked a number of questions about your general health, your symptoms relating to haemorrhoids, such as pain and incontinence and any complications you may have experienced (20-25 minutes)
- 5) One year after your treatment - to answer some of the same questions that you have been asked before and some questions to see if your haemorrhoids have come back since being in the study (5-10 minutes).

One year after your treatment, the research nurse will also look at your hospital notes to see if you have been back to the hospital for treatment of your haemorrhoids, they will ask your consultant if you have been back for treatment and they will write to your GP to see if you have been to see them about your haemorrhoids. This is so we can see if you have needed any further treatment for haemorrhoids since taking part in the research.

At the moment this is the plan for the research but we may want to contact you again in two-five years time if we still need to know how you are keeping. Please indicate you are happy to be contacted for long-term follow-up on the consent form (point 6).

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What are the alternatives for treatment?

There may be other options for the treatment of your haemorrhoids and these can be discussed with your doctor before deciding whether to take part in the research.

What are the possible disadvantages and risks of taking part?

[Both of the treatments are routinely offered in the NHS; both would be options offered to you if you did not take part in the trial and are considered to be safe treatments.]

or

[Although we do not currently offer Haemorrhoidal Arterial Ligation in this trust, both of the treatments are routinely offered in other NHS trusts and are considered safe treatments.]

Delete as applicable to account for local variation

The Rubber Band Ligation treatment group

There is a potential for rubber band ligation to not resolve your haemorrhoidal symptoms. You may require further banding or indeed an alternative procedure if this is the case.

The Haemorrhoidal Artery Ligation treatment group

Potential disadvantages/risks may include post-operative pain, but these can usually be resolved with pain-reducing drugs. There is also a small chance of recurrence.

What are the side effects of any treatment received when taking part?

There are a number of possible side effects and some rarer outcomes associated with both of these treatments, and also with the anaesthetic required for Haemorrhoidal Arterial Ligation. Please speak to your doctor if you would like to discuss these further.

The Rubber Band Ligation treatment group:

Very common (affecting more than 1 in 10 patients) outcomes following this procedure include mild to moderate pain, which is common for a few hours after the procedure and recurrence (need for further banding).

Common outcomes following this procedure include bleeding (usually mild and self-limiting) and fainting (affecting approximately 1 in 25 people).

Uncommon complications include admission to hospital for bleeding requiring blood transfusion (affecting less than 1 in 500 people) and admission to hospital for pain, usually necessitating removal of bands (affecting approximately 1 in 100 people).

Very rare (affecting less than 1 in 10,000 people) complications include severe infection.

The Haemorrhoidal Artery Ligation treatment group:

Common (affecting less than 1 in 10 patients) outcomes following this operation include pain, bleeding, anal fissure and pain on defaecation.

Uncommon (affecting less than 1 in 100 patients) outcomes following this operation are postoperative haemorrhage (which may on rare occasions include the need for a blood transfusion), bleeding requiring re-admission to hospital and recurrence of haemorrhoids.

Rare (occur in less than 1 in 1,000 people) complications could include urinary retention, pelvic sepsis, pelvic abscess, anal stenosis, faecal incontinence and systemic complications.

Side effects and complications of anaesthetic:

Common (affecting less than 1 in 10 patients) side effects from anaesthetic include:

Feeling sick and vomiting, sore throat, dizziness, blurred vision, headaches, bladder problems, minor damage to lips or tongue, itching, aches and pains, pain during injection for drugs, bruising and soreness, confusion and memory loss.

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Uncommon (affecting less than 1 in 100 patients) side effects from anaesthetic include: Chest infection, muscle pains, slow breathing, damage to teeth, an existing medical condition getting worse.

Rare or very rare (affecting less than 1 in 1,000 or 1 in 10,000 people) complications are: Damage to the eyes, heart attack or stroke, serious allergy to drugs, nerve damage, equipment failure. Deaths caused by anaesthesia are very rare. There are probably about five deaths for every million anaesthetics in the UK.

What are the possible benefits of taking part?

You will receive proper health care by your consultant whether you choose to participate in the study or not. We do not know which type of surgery will be better for you in the long term. This is the reason for doing this research; HubBLE is therefore an important study. If either surgery is found to be more beneficial than the other, this will become the treatment of choice for people with haemorrhoids. By taking part in this study you will be directly helping us to inform the treatment of future patients diagnosed with haemorrhoids that need surgical treatment.

What happens when the research study stops?

Your colorectal surgeon will continue your care and treatment.

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

You can withdraw from the study at any time, but you will still need to attend clinical appointments so that you can have your haemorrhoids monitored as part of your usual care. We will keep your data up until the point that you withdraw and we will not collect any more information from you.

What if there is a problem?

We do not think that taking part in this research will be different to receiving treatment outside the study but if you have a concern about any aspect of this study, you should ask to speak to your surgeon or the research nurse who will do their best to answer your questions, or contact the study team (contact details below).

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

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 Sheffield Teaching Hospital NHS Foundation Trust or LOCAL NHS Trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (PALS local details).

Will my taking part in this study be kept confidential?

All information that is collected about you will be kept strictly confidential and will be held securely in line with the Data Protection Act. Members of the local research team and the research team at the University of Sheffield will have access to your personal details so that you can be contacted over the telephone and sent questionnaires. Any personal details will be kept separately to your questionnaire responses and linked only by a research study number. If you participate in the trial, we will notify your GP, unless you prefer that your GP is not informed. We will also contact your GP and consultant 12 months after you have had your treatment to confirm any subsequent treatment you may have received.

At the end of the study data will be sent to the University of Sheffield where it will be stored in a secure area and also kept as a password-protected computer file, both of which can only be accessed by the research team, the research sponsor and regulatory authorities. Data for all participants in the study, including those who withdraw, will be kept for a minimum of 15 years.

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An anonymous (with any details that might identify you removed) computer file will be retained and made available to other researchers for use in future studies.

If you join the study, some parts of your medical records and the data collected for the study may be looked at by authorised persons from Sheffield Teaching Hospitals NHS Foundation Trust and the University of Sheffield. They may also be looked at by representatives of regulatory authorities and by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

Involvement of the General Practitioner/Family doctor (GP)

With your permission, we will inform your GP that you are taking part in this research. We will also contact them one year after you have received your treatment to see if you have seen them in relation to your haemorrhoids.

What will happen to the results of the research study?

The results of the study will be used to standardise surgical procedures for patients with haemorrhoids. These findings will also be published in scientific journals and presented at scientific meetings. The findings will also be made available to patients through patient organisations, health information websites that are open to the public and the media where possible and appropriate.

The study website (<http://www.shef.ac.uk/scharr/sections/dts/ctru/hubble>) will publish a summary of the results following completion of the study. This will be published in spring 2015; please check the website for details.

Who is organising and funding the research?

The study has been designed by UK colorectal surgeons and researchers. It is sponsored by Sheffield Teaching Hospitals NHS Foundation Trust, and managed by the Clinical Trials Unit at the University of Sheffield. Patients will be recruited at different hospitals throughout the UK. The study is being funded by the UK National Institute for Health Research (NIHR), Health Technology Assessment (HTA) Programme.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by South Yorkshire Research Ethics Committee.

Thank you

Patients and doctors rely increasingly on the results of clinical studies, such as HubBLE, to make sure they are making the right decisions about treatment. Thank you for taking the time to read this information sheet, we hope that it has been helpful in enabling you to decide if you would like to participate in the HubBLE study.

Further information and contact details

Central Office Contact Details:

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Local Contact Details:

To add local details