Patient Information Sheet

Northumbria Healthcare NHS Foundation Trust Foot and Ankle Unit

COSMIC study - A comparison between Open and Minimally Invasive Surgery for Hallux Valgus (Bunion) Correction

Research Study reference: 16/NE/049

We would like to invite you to take part in our research study

Before you decide we would like you to understand why the research is being done and what it would involve for you

Part 1 tells you the purpose of the study and what will happen if you take part. Part 2 gives more detailed information about the conduct of the study

One of our team will be happy to go through this with you and answer any questions you may have

Part 1

What is the purpose of the study?

Bunion correction surgery has traditionally been performed by making an approximately 15cm long cut on the inside of the foot, known as an 'open procedure' with good results. Over recent years, there has been a move to achieve the same results of surgery though small keyhole incisions, known as a 'minimally invasive procedures'. Both of these procedures are now performed regularly at Northumbria Healthcare Foundation Trust.

The purpose of this study is to discover whether patients have a preference for the type of bunion surgery they have. We also want to discover whether one surgical technique produces better results for patients than the other.

Why have I been invited to take part?

You have been invited to take part as your surgeon thinks that your bunion would be suitable to be corrected by either an open procedure or by a minimally invasive procedure.

Do I have to take part?

No, it is up to you whether or not to take part. If you decide to take part you will be given this information sheet to keep for reference and be asked to sign a consent form. You may decide to withdraw at anytime during the study, without having to give a reason.

If you decide not to take part, or if you withdraw during the study, this will not affect the standard of care you receive. Whatever your decision, your legal rights as a patient receiving treatment under the National Health Service will not be affected in any way.

What will happen to me if I take part?

If you choose to take part you will be randomly allocated to have either an open surgical procedure or a minimally invasive surgical procedure. This means that a computer programme will be used to allocate your procedure. This process is known as randomisation.

The computer programme is not making any clinical decisions about your care. In fact it is being used to ensure that the study is being conducted scientifically and without bias

You can be reassured that you will only be eligible to be included in the study if your surgeon has decided that either surgical procedure is suitable for you. It is

important that you are totally happy with either surgical procedure before you commit to taking part in the study.

For both procedures, the follow-up plan is exactly the same whichever surgical procedure has been performed.

You will be asked to fill out a questionnaire before your surgery, at 6 months after surgery and we will contact you one year after surgery by telephone to complete a final questionnaire.

What exactly would the study involve?

If you choose to take part you will be asked to fill out a questionnaire before your surgery, which will take around 5 minutes to complete. We will also measure the range of movement you have in your joint before you have any surgery.

After either surgical procedure you will be likely to go home the same day. The advice and regime following surgery are exactly the same whichever surgical procedure has been performed. Your foot will have a dressing in place and be placed in a heel weight bearing shoe.

You will be seen again at 2 weeks for removal of the dressing, to check the wound and you will be placed in a light splint inside the heel weight bearing shoe, at this stage you will be encouraged to get the toe moving.

At 6 weeks in clinic, we will measure the range of movement you have in your joint again. At this stage you will be able to wear a normal shoe, although you will be asked to continue wearing the splint until 3 months after your operation.

We will then see you at 6 months in the outpatients clinic. Once again we will measure the range of movement in your joint, and ask you to complete a questionnaire.

Finally at 1 year after your operation the research nurse will contact you to complete questionnaire by telephone follow up.

In addition, as part of the consent process we ask your permission to access information from any X-rays or scans taken which are available as part of your routine care. However, we are not asking for you to have any x-rays or scans for research purposes.

What are the possible benefits of taking part?

There are no direct benefits from taking part in the study.
However, we hope that the information we obtain from the study will help further research in bunion surgical procedures.

What are the possible risks of taking part?

There are no identified risks to taking part in the study as the information we are collecting for the study consists of measuring the range of movement of your joint and collecting your questionnaire responses are therefore are not likely to carry any risks.

The risks from the two surgical procedures themselves are the same for non-study participants as for study participants. The main complications of both surgical procedures are wound infection, fracture, pain, failure of fixation, removal of metalwork in the future and recurrence of the deformity.

We are also collecting details of any complications which may arise from surgery. This information will also help inform us as to which surgical technique patients get the best results from.

If you are considering taking part in the study please read the additional information in Part 2

Part 2

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

If you decide to withdraw from the study, we will use the information obtained up to that point. Any further follow-up appointments will be arranged for the sole purpose of your care and no further information will be collected for research purposes.

What if there's a problem?

Every care will be taken in the course of the study, if you have a concern about any aspect of the study, you should ask to speak to your surgeon or the study team who will do their best to answer your questions. If you remain unhappy and wish to complain, you can do this by the normal NHS complaints procedure.

Will my taking part in the study be kept confidential?

The information collected during the course of the procedure will be kept confidential. The results of the study may be used for publication or presentation. Should this occur, your data would be anonymised with your personal details, such as your name, address and date of birth removed so you cannot be recognised. Only your surgeon and the clinical team responsible for your care will have access to your personal information.

What will happen to the results of the research study?

It is anticipated that theresults of the study will be presented and published in a medical journal. If you are interested in obtaining a copy of the results at the end of the study, please feel free to contact the research team at the address provided.

Who is organising and funding the study?

This research is being conducted independently. It has not received any funding from a private company and none of the study investigators stand to gain financial benefit from the results of the study.

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 _____ opinion by the Research ethics committee.

Contact us:

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