NHS
The Royal
Orthopaedic Hospital
NHS Foundation Trust

Participant Information Sheet

Study title: MyPAO patient specific guides and surgical planning for periacetabular osteotomy
IRAS Number: 318218

Invitation

We would like to invite you to take part in this study. Before deciding if you would like to take part you need to understand why the research is being done and what it will involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish before making your decision to take part.

Once you have read this information sheet a member of our team will go through the information with you and answer any questions you may have.

Background

Your hip joint has two bones that fit together like a ball in a socket, see figure 1.

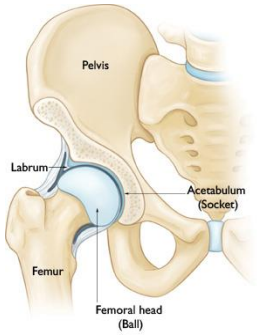

Figure 1 – Normal Hip Joint

The bones that make the ball and socket joint are not the same shape in everyone. In some people the socket is shallow which can overload the joint and cause pain. This condition is caused hip dysplasia, and one of the treatments for this is an operation called a peri acetabular osteotomy. This involves cutting the bone around the socket, and moving the socket so it better covers the femoral head. This is a complex process and the surgeon will use x-ray to guide where to move the socket to.

Why am I being approached to take part?

You are being approached as you have been identified as having hip dysplasia and you have been listed for a peri acetabular osteotomy.
We are inviting 15 patients like you with hip dysplasia undergoing acetabular osteotomy to take part in the study.

Why is this study being done?

A new technology called MyPAO™ analyses your pre operative CT scans allowing your surgeon to plan the best position to move your socket to. It also allows for custom made surgical guides to be made for use in your surgery, with the aim being to help the surgeon move your socket to the optimum position. These surgical guides have receive a CE marking and there have been no adverse events related to their use. Once the bone is in the correct position these guides are removed from your body. The bone is fixed with normal surgical quality screws. While custom made surgical guides have been used extensively in other areas of surgery, such as for knee replacements, the technology has never before been used for your type of surgery.
We are conducting a study to confirm the safety of the technology in this particular operation and to improve the surgical technique before more widespread use.

Do I have to take part?

No. It is up to you whether or not to take part in this research. If you decide not to take part, you may do so without providing a reason. If you do decide to take part you are still free to withdraw at any time and 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 you receive. If you decide not to take part or wish to remove yourself from the study you will receive standard surgical care.

What will happen if I do take part?

If you do decide to take part you will be asked to sign a consent form.
To plan the operation, the images from your routine pre-operative CT scan will be sent to Medacta International, a company in Switzerland who manufacture the custom-made surgical guides. These images will contain at least two pieces of information which could identify you (for example, your name or date of birth) but these will only be seen by Medacta employees to plan your operation and will not be shared with any other party. This information will be managed through a secure portal and covered by individual agreements and information governance approvals between your NHS hospital and Medacta. Your GP will be informed of your involvement.

Your operation will be conducted exactly as it would if you weren't part of the study, except that the surgeon will have the use of the guides to help them. After surgery you will be seen in the Outpatients department for routine follow-up visits at 6 weeks, 12 weeks, 6 months and 12 months.

During these visits a research nurse will see you to ask you to complete some questionnaires asking about your symptoms and if you have had any surgical complications.

What are the possible benefits of taking part?

Custom made surgical guides are designed to improve the accuracy with which your surgeon performs your operation which we hope would lead to better function, however this cannot be guaranteed.

What are the possible disadvantages and risks of taking part?

Acetabular osteotomy is a major operation and the risks of surgery will have been explained by your surgeon. They include risk of bleeding, infection, damage to nerves and blood vessels, problems with the bones healing and ongoing pain.
It is possible that the surgical guides do not fit you as expected. If this is the case the surgeon will continue with the operation by conventional means. It is also possible the surgical guides may break if not used properly. If this occurs the broken guides would be removed from you and the operation completed by standard means. There have been no reports of this happening; we estimate the chances of this occurring to be less than 1 in 100. As this technology has only recently been used in this type of operation, it is possible that there are risks that we do not know of yet.
We do not believe there are any specific risks of participating in this study outside of those involved in the surgery itself.

What if new information becomes available?

Sometimes during the course of a study, new information becomes available about the treatments that are being studied. If this happens, someone will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, you can discuss your continued care with your doctor.

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 providing a reason. Withdrawing from the project will not affect the standard or type of care that you receive and you will continue to be managed according to our routine standards of care. You will need to speak to your clinician or use the contact information below to inform a member of the research team that you wish to withdraw from the project. This is to ensure that no further data is collected for research purposes.

How will my information be kept confidential?

All information which is collected about you during the course of the research will be kept strictly confidential. Personal data including your name, initials, date of birth/age, address and hospital

number will be used by The Royal Orthopaedic Hospital research team to search and find the relevant data from within the hospital. If you provide your consent to take part in the project, we will add your initials to a study log which will allow us to allocate you a unique study ID number. All data about you collected for this project will be identified using this unique study reference number, which will mean that you will not be able to be identified from the data used in the analysis or from any publication of the results. Any paper copies of your data will be kept in locked filing cabinets or in password-protected computer databases accessible only to essential research personnel at The Royal Orthopaedic Hospital NHS Foundation Trust.

The Royal Orthopaedic Hospital NHS Foundation Trust is the sponsor for this study based in the UK. We will be using information from yourself and your medical records in order to undertake this study and will act as the data controller for the study. This means that we are responsible for looking after your information and using it properly.

We will use your name, NHS number, initials and date of birth to make sure that relevant information about the study is recorded for your care, to oversee the quality of the study and audit the data collection process.

The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number, date of birth or contact details.

In order to create the custom made guides your routine pre-operative CT scan will be sent to Medacta International, a company in Switzerland who manufacture the guides. These images will contain at least two pieces of information which could identify you (for example, your name or date of birth) but these will only be seen by Medacta employees to plan your operation and will not be shared with any other party. This information will be managed through a secure portal and covered by individual agreements and information governance approvals between your NHS hospital and Medacta. The CT images will be held on Medacata's secure servers and is only accessible to employees involved in creating your surgical guides. After your surgery is complete the images will be removed. In some other areas of surgery; for example custom made knee replacement cutting guides these processes are already used by the NHS and Medacta.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you. If you withdraw from the study, we will keep the information about you that we have anonymised already. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information, please contact the Research and Development department on 0121 685 4316.

You can find out more information about how your information is used:

- www.roh.nhs.uk/about-us/corporate-information/data-and-confidentiality
- *www.hra.nhs.uk/information-about-patients/*
- Asking one of the research team

- Speaking to our patient advice liaison service by Emailing: roh-tr.PALS@nhs.net or telephoning 0121 685 4128
- Speaking to the Royal Orthopaedic Hospitals Research Governance Manager: 0121 685 4000

What will happen to the results of the research study?

The results of the study will be collated and analysed by the sponsor and members of the research team and be published in scientific journals. You will not be personally identified in any report or publication.

Who is organising and funding this study?

The research project is sponsored and organised by the Royal Orthopaedic Hospital NHS Foundation Trust. The project is being funded by Medacta International, the company that manufacture the custom made surgical guides.

Who has reviewed this study?

This study has been reviewed and approved by ***North West - Liverpool Central Research Ethics Committee***, which has responsibility for scrutinising all proposals for medical research on humans, has examined the proposal and has raised no objections from the point of view of research ethics. It is a requirement that your records in this research, together with any relevant medical records, be made available for scrutiny by monitors from the sponsor, The Royal Orthopaedic Hospital NHS Foundation Trust, whose role is to check that research is properly conducted and the interests of those taking part are adequately protected.

What happens if something goes wrong?

In the event that something goes wrong and you are harmed during the research due to someone's negligence, then you may have grounds for legal action for compensation. If you feel that this is the case, please contact the Research Governance Team on 0121 685 4316.

Who should I contact if I wish to make a complaint?

Any complaint about the way you have been dealt with during the study or any possible harm you might have suffered will be addressed. Please address your complaint to the person below, who is entirely independent of this study:

For independent advice contact the PALS service (Patient Advice Liaison Service) at ROH-TR.PALS@nhs.net - 0121 685 4128 or follow the NHS complaints procedure.

Further information and contact details

If you would like further information regarding the research project, or would like to be given access to a copy of the results when they are available, you may contact one of the following:

Chief Investigator:
Mr Peter Wall
Consultant Orthopaedic Surgeon
Tel: 0121 685

Or

Mrs Ellie Keeling
Research Nurse
0121 685 4316

Thank you for considering participation in this study and for taking the time to read this information sheet