[Local NHS trust logo]

The World Hip Trauma Evaluation Five– Main Study

A randomised controlled trial comparing contemporary uncemented hemiarthroplasty with standard-of-care cemented hemiarthroplasty for the treatment of displaced intracapsular hip fractures.

Patient Information Sheet

Background information

We would like to invite you to take part in a research study investigating two different ways of treating a broken hip. Before you decide whether to take part in the trial we would like to explain why the research is being done and what it would involve for you. One of our team will go through the sheet with you and answer any questions you have.

The type of hip fracture you have sustained is best treated with a partial hip replacement (also called a hemi-arthroplasty). The hemi-arthroplasty implant is inserted into the thigh bone and replaces the 'ball' part of the 'ball-and-socket' hip joint. The 'socket' part is not replaced.

What is the purpose of this trial?

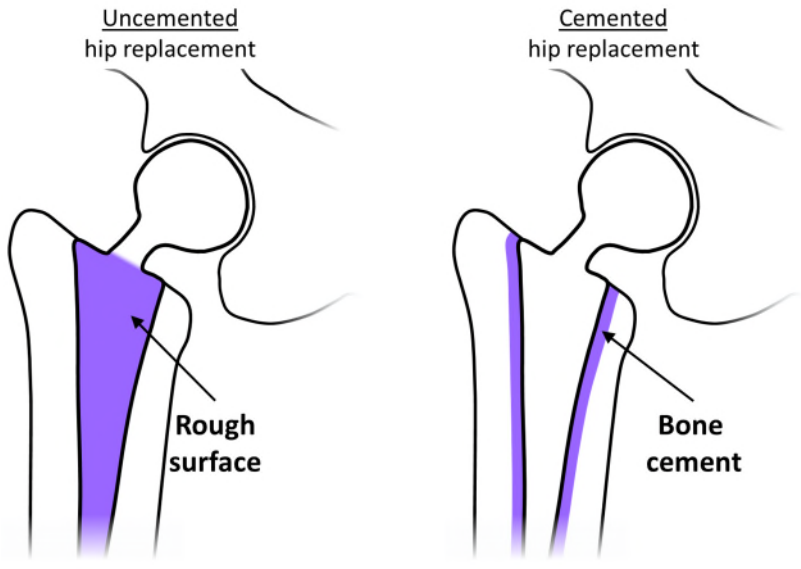
This is a study that compares two types of hip replacement (hemi-arthroplasty), and will tell us if there is any difference in patients' quality of life when their hip fracture is treated with one of two common operations. The information gained will help patients and their doctors make more informed decisions about the best type of treatment for this injury.

Why have I been invited to take part?

You have been invited to take part in this trial because you have a broken hip that will be treated with a hip hemi-arthroplasty. Patients with the same type of injury in several NHS hospitals are being invited to take part.

What is the difference between the hip implants?

Both treatments involve placing an implant into the top of the thigh bone to replace the ball of the hip joint. There are two ways to fix the hip hemi-arthroplasty to the bone – either with or without 'bone cement'. At the moment the treatment used in most hospitals is the cemented implant, which uses bone cement to hold the implant in place. However, some hospitals in the UK and abroad only use uncemented implants that have a special rough surface coating to help the implant attach to your thigh bone and therefore doesn't require bone cement. At present, it is not clear which treatment is better for patients in terms of how well the implant performs. The diagram on the next page will give you an idea of what each implant looks like.



Which treatment will I be given?

Independently of the trial a consultant orthopaedic surgeon has decided that your type of injury would be best treated with a partial hip replacement (hip hemi-arthroplasty). If you decide to take part in the study a computer will assign you to be treated with either a cemented or uncemented hip hemi-arthroplasty. You will have the same chance of receiving either treatment, but at this stage of the trial we are not able to tell you which of the two treatments you will receive. This is done so that we don't influence your opinions about your treatment. However, if you would like to know then we can tell you at the end of the trial.

What will happen if I decide to take part?

If you decide you would like to be involved in the research study, you will be asked to sign a consent form, after which we will ask you to fill out a questionnaire. The questionnaire will ask you about how well you were able to perform certain day-to-day activities before your injury occurred. The questions should take about 5 minutes to complete. You will then receive your allocated surgery, according to standard NHS guidelines. Throughout the study you will be treated in the usual way. The only additional commitment we ask is that you fill out the same short questionnaire to tell us about your recovery at 1, 4 and 12 months after your surgery. You can answer the questions over the phone and if we are unable to reach you on the phone, we will send you the questionnaire by post or electronically. If we are unable to contact you after multiple attempts, we will use the alternate contact details you have given us, and ask your GP to confirm your contact details. Anonymised copies of sections of your medical notes that are relevant to this research, such as operation notes, blood pressure measurements routinely taken during surgery, and discharge summaries, will be sent to the trial office at the University of Oxford.

This study is linked to a wider study (called the World Hip Trauma Evaluation – WHiTE) to measure the recovery of patients with all of the different types of broken hip at hospitals across the UK. We would like your permission to use the information collected for this study as part of this wider project. The inclusion of your data in our wider study is completely optional and, should you choose not to do so, this will not affect your participation in this study. If you would like further information on the wider study, please ask the research team who will be happy to provide this.

Do I have to take part?

No, it is entirely your decision whether you choose to take part or not. If you agree to take part now you are still free to withdraw at any time and without giving a reason. A decision not to take part or to withdraw later will not affect the standard of care you receive.

What are the possible disadvantages and risks of taking part?

Any operation for a broken hip carries some risks. The risks of surgery with both implants include: bleeding, infection, further fracture, dislocation, leg length discrepancy, blood clots, damage to nerves and blood vessels, and the risks associated with the anaesthetic. These risks are the same as for patients who are not part of this research project. There are also uncommon risks associated with each type of hip replacement. In a small number of cases, patients having a cemented replacement can have a reaction to the bone cement, and in a small number of uncemented replacements there may be an extension of the fracture during surgery. If either event were to occur, the anaesthetist and surgeon would continue treatment as per normal practice.

You will have routine X-rays taken of your hip before and after the operation, to evaluate the hip replacement. The dose of radiation you will receive is equivalent to around 3.6 months of normal background radiation and is the same patients who have either hip replacement operation.

What are the possible benefits of taking part?

There is no specific advantage to you from taking part in the trial. However, the information we get from this trial will help us to decide which treatment is best for patients with this type of injury.

What happens when the research trial ends?

After you have completed your final questionnaire (about 12 months after your injury) then you will have completed your involvement in the trial. If you are having medical problems during or after the trial then your clinical care team will arrange for you to have an appointment with an appropriate specialist to continue your care.

What happens to the information?

Your personal details will be held by the research team at University of Oxford. We will remove any details that would identify you personally (such as your name, date of birth, etc.) from your answers to our questions and no individual results will be published.

We may share limited personal information (e.g. your NHS number, sex, date of birth and postcode) with appropriate organisations (including, but not limited to, NHS Digital, Office of National Statistics, Clinical Practice Research Datalink) in order to link your study data to specific records related to the research held in other databases. We will use the records from these databases to get information about mortality, as part of the main outcome of the study, to find out about other medical conditions so that we can take this into account when analysing the results of the study, and to look at NHS resource use. We plan to compare the results of our study with other national and international hip fracture studies. We will also share information with the National Hip Fracture Database. All information that is collected during the course of the research will be used and stored in accordance with the most up to date data protection legislation.

What happens to my personal data?

Any data from which you can be identified, such as your name, gender, date of birth, or data concerning your health, is known as personal data. The University of Oxford, as sponsor, is the data controller. This means that we, as University of Oxford researchers, are responsible for looking after your information and using it properly. We will use the minimum personally-identifiable information possible. We will keep identifiable information about you for 12 months after the study has finished. We will store the anonymised research data and any research documents with personal information, such as consent forms, securely at the University of Oxford for a minimum of 10 years after the end of the study. Your rights to access, change, or move your personal information may be limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate.

Your personal data will only be used as we explained it in this information sheet, and research is a task that we perform in the public interest. If you are concerned about how your personal data is being used, please contact the study team using the contact details at the end of this information sheet.

With your consent we will notify your GP and other doctors who may treat you, but who are not part of this trial, that you are taking part. When the results of the study are reported or published, it will not be possible to identify the individuals who have taken part in any way.

What will happen to the results of the research trial?

During the course of the trial we will publish the findings in medical journals and at conferences. You will not be identified in any reports or publications resulting from the trial. If you would like a copy of the published results, please ask member of the research team or your surgeon. Copies of patient newsletters will be available in the orthopaedic wards of participating hospitals.

What if new information becomes available?

If there is important new information about the treatments being studied then the research team will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, we will encourage you to discuss your continued care with your doctor. If you continue in the study you may be asked sign an updated consent form.

Who is organising and funding this trial?

The study is being organised by Professor Matt Costa (the Chief Investigator) at the University of Oxford (the Sponsor). This study is funded by the National Institute for Health Research's Research for Patient Benefit programme (reference PB-PG-0215-36043).

Who has reviewed this trial?

This trial has been reviewed by the Wales Research Ethics Committee 5 and was given ethical approval on 22 November 2017 with reference number 17-WA-0383.

What happens if I have concerns?

The University of Oxford has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this trial. NHS indemnity covers you for the clinical treatment with which you are provided.

If you have concerns about any aspect of this study, you should contact Professor Matt Costa who is the overall lead of this trial on 01865 223114 or matthew.costa@ndorms.ox.ac.uk. You may also contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 616480 or ctrg@admin.ox.ac.uk.

Contacts

If, at any time, you would like further information about this research project you may contact your local research lead (specialist nurse) [researcher name] on [telephone] or [email], or [name] (the trial manager based at The University of Oxford) on [telephone], or white5@ndorms.ox.ac.uk.

For independent advice contact the PALS service (Patient Advice Liaison Service) on [telephone]. PALS is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. However, PALS cannot provide specific information about this research trial.