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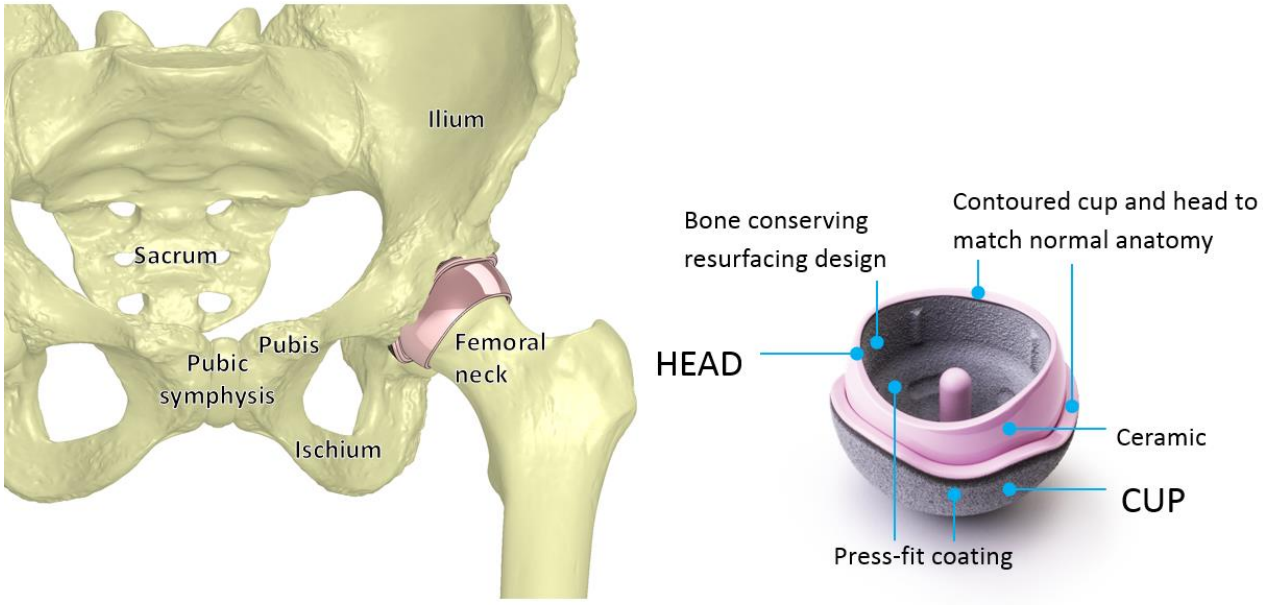
H1 HIP RESURFACING ARTHROPLASTY

Cohort 1B

Patient Information Sheet

Version 2, 05.10.2020



H1 ceramic-on-ceramic hip resurfacing

INVITATION

We would like to invite you to take part in our research study involving a new hip implant. Before you decide, 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 information carefully and discuss it with others if you wish. 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?

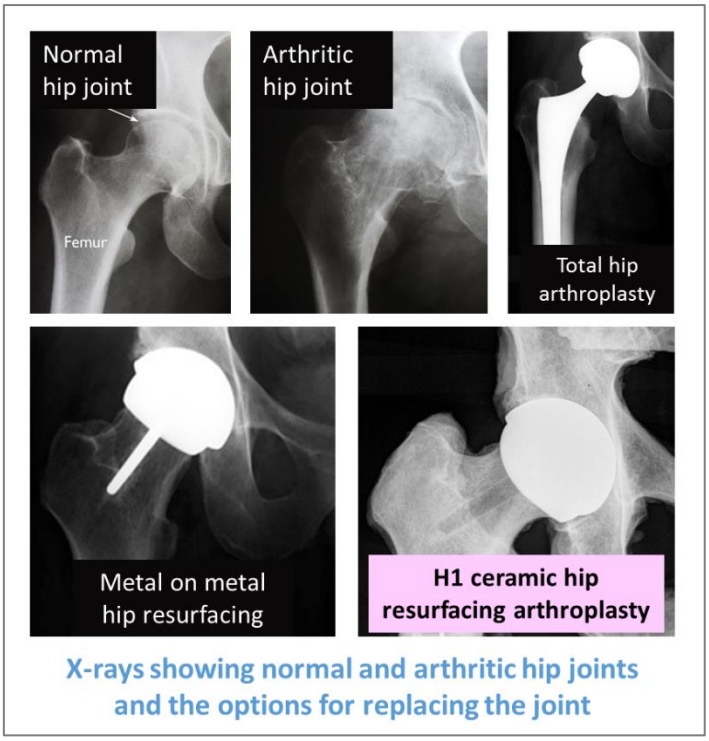
Our primary intention is to assess the short, mid and long term safety and function of the new H1 Hip Resurfacing Arthroplasty (H1 HRA). Your surgeon will plan and perform your operation as per standard practice.

WHAT IS HIP RESURFACING ARTHROPLASTY?

Arthroplasty means "surgical replacement of a joint", and is carried out on joints with diseases such as arthritis. When performing a hip resurfacing arthroplasty (HRA), the surgeon only removes the diseased cartilage of the hip joint and replaces it with an implant that re-covers the smooth connecting surfaces in the pelvis and on the head of the thigh bone. This is different from a conventional total hip arthroplasty (THA) where the head of the thigh bone is removed and a metal stem is placed inside the thigh bone. HRA preserves more of the native anatomy than THA. Metal-on-metal HRAs have been shown to be safe and effective in many patients. However, in some metal-on-metal HRAs, metal particles are generated by wear of the implant, causing tissue reactions around the hip.

WHY HAVE I BEEN INVITED?

You are someone who has arthritis and may be suitable to have a hip resurfacing arthroplasty instead of a total hip arthroplasty.



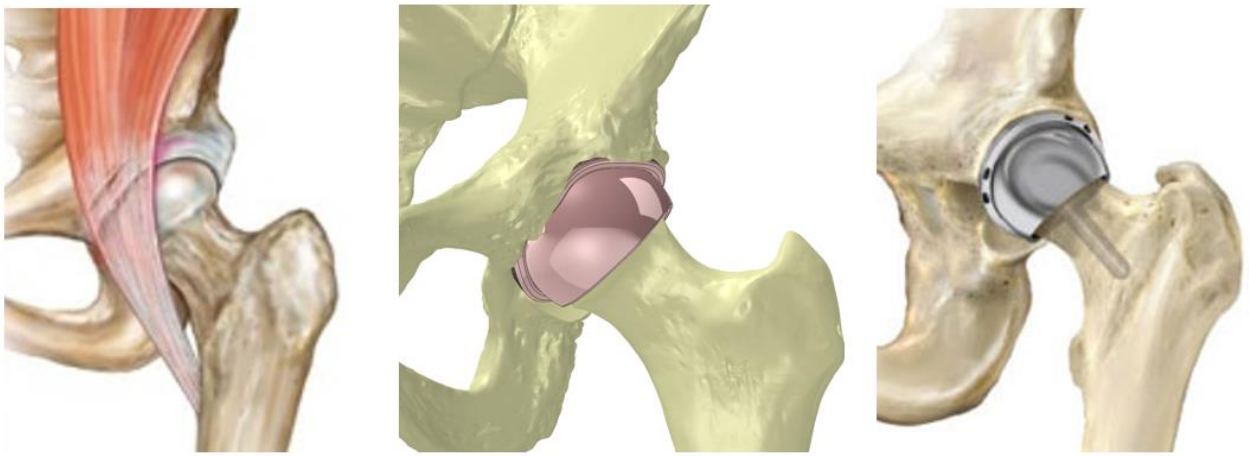
X-rays showing normal and arthritic hip joints and the options for replacing the joint

WHAT IS THE H1 HIP RESURFACING ARTHROPLASTY?

The H1 HRA study has undergone review and approval from the applicable European Union (EU) regulatory bodies but the H1 device is not yet CE marked (CE marking is a symbol shown on devices, demonstrating that they conform with relevant EU directives regarding health and safety or environmental protection). The H1 HRA shares many features with other HRA devices that have demonstrated long term clinical success. The H1 HRA has two features which are unique:

1. It is a hip resurfacing device that does not have a metal-on-metal articulation. Instead the H1 is made of a ceramic that is strong, low wearing and non-toxic. By swapping the metal material of normal HRAs with ceramic, the advantages of HRA are kept, while the possibility of clinical problems arising from metal ion released by the articulation is removed.

2. The H1 HRA has been designed to reduce the likelihood of tendon rubbing, which can be painful, as it causes swelling and soreness. This rubbing can occur even during normal motion, and the shape of the H1 HRA has been designed to avoid this happening.



Location of the potential tendon impingement (left). Reduced protrusion owing to the contoured head and cup of the H1 (middle). Overhang of traditional metal hip resurfacings (right),

We must stress that these benefits, and potential downsides of the H1 HRA, are currently not confirmed: they will be evaluated in this study.

DO I HAVE TO TAKE PART?

No. It is entirely up to you. If you would like to take part, you will be asked to sign a consent form. Even after you have signed this consent form and agreed to join the study, you are free to withdraw from the study at any time without giving any reason. If you decide not to take part or withdraw from the study, it will not affect your current or future treatment by this department in any way. At all times we will aim to give you the best possible treatment. We will inform your GP of your participation within the research, if you decide to take part and agree to inform your GP. Patients who have private medical insurance are advised to inform their insurance company of their participation in the study.

WHAT WILL HAPPEN TO ME IF I TAKE PART?

Agreeing to take part in this study will have no effect on the date of your surgery, which will be determined by your hospital as per normal practice. As part of routine practice you would normally have an X-ray pre-operatively and post-operatively immediately after surgery. As part of this study, the following events will take place in addition to the standard of care you would receive at your hospital:

- You may be asked to undertake a DEXA scan to measure bone mineral density (BMD) in the spine and hips. DEXA scans use X-rays to assess bone health and diagnose osteoporosis, an age related bone wasting disease that causes bones to become fragile and fracture. Participants with a low BMD might be at risk of a fracture and are ineligible for the trial.
- Demographic information and medical history will be recorded before surgery.
- X-rays of your hip will be taken post-operatively at 3 years, 5 years and 10 years.
- CT scans of your hip will be performed pre-operatively and post-operatively, at 2 days, 6 weeks, 3 months, 6 months, 9months, 1 year and 2 years. The CT scan at 6 weeks will replace the X-ray that would normally have been given in your routine care.
- You will be asked to complete questionnaires (EQ5D, Oxford Hip Score, Imperial Score) to evaluate your hip function (you can choose to complete this onsite or at your own convenience) and your surgeon will conduct a paper based questionnaire (Harris Hip Score), before surgery and after surgery at 6 weeks, 3 months, 6 months, 9 months, 1 year, 2 years, 3 years, 5 years, 7 years and 10 years.
- During your surgery, your surgeon will also fix very small beads (less than 1mm), into the bones of the hip and femur, which will allow us to detect any movement of the implant on the bone on your CT scans. This technique is a safe and established method for monitoring new implants. The beads will not impact your surgery and will not affect your hip movement or recovery.
- The remaining follow up visits are scheduled post-operatively at 4, 6, 8 and 9 years. You will not be required to attend a hospital visit. The data collected will include questionnaires (EQ5D, Oxford Hip Score, Imperial Score). The questionnaires will be collected via phone call/email/post/online.
- **Optional Assessment**: Treadmill gait analysis (available at Charing Cross Hospital only) will be performed pre-operatively (reflective markers only) and post-operatively at 1 and 5 years. This is not mandatory for taking part in this research study and you can freely opt out of the gait assessment and the additional measurements described here:
    - Your leg measurements will be taken
    - You will also be asked to walk on a treadmill and asked to carry out several tasks, including walking on the flat surface and uphill. We will modify the speed and the slope of the treadmill within the limits of your comfort, to assess how you walk and what you feel comfortable with.
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N.B. You will need to bring a pair of comfortable walking shoes for the treadmill assessment.

The H1 implant is available only as part of this research study, which means that the appropriate implant size may not be available for you. If this is the case you will not be able to take part in this study.

A final evaluation will occur at the end of the 10 year follow-up study. At this point if deemed necessary you may be required to attend further follow-up appointments, at 15 and 20 years after surgery. The extent of these follow-up appointments will be discussed with you by the research team and you will be given the opportunity to ask questions and resolve any queries you may have. In the event a revision surgery is required to remove the H1 implant, we will ask your permission via the H1 consent form to retain and store any surplus (excess) tissue removed along with the H1 implant to be kept as part of this trial. The tissue will be stored using the study idenfication number at Imperial College London, MSk Lab, Sir Michael Uren Hub, White City Campus, London W12 0BZ.

We would also like to remind you to avoid high impact exercise such as running, tennis and outdoor cycling until at least 6 months after your surgery. This is routine advice given to any patient who has undergone hip surgery and we recommend discussing with your surgeon before restarting these activities.

WHAT ARE THE SIDE EFFECTS, AND ARE THERE ANY RISKS IN TAKING PART?

Any operation to replace or resurface the hip carries risks, so the decision to proceed with a hip arthroplasty of any sort needs to be taken with caution. The potential benefit of a pain free hip has to be balanced with the risks of the operation causing an unexpected problem of some sort. Complications can be described in two major categories: those which are general to all hip operations, and those which are specific to a hip resurfacing with the H1 device.

General complications, which are rare, but occur with any form of hip arthroplasty include: venous thrombosis or embolism, fracture of the femur or pelvis, infection, heart attack, stroke, nerve damage and death.

The main specific complications that may occur with the H1 are of component fracture or loosening or squeaking of the ceramic bearing. While ceramic fracture is possible, we expect the likelihood of occurrence to be rare given that the device is designed to withstand a greater force than that needed to break human bone and that every device is individually inspected and tested prior to leaving the factory to identify any cracks.

The H1 might become loose if the coating detaches from the ceramic material. This is expected to be rare because the device coating is designed to stay attached to the device, and tests have confirmed this. However because the device hasn't been tested in humans it is unknown whether device loosening may occur. The H1 might also become loose if the coating fails to bond with the bone. This is also expected to be rare as the coating used is very similar to the coatings which have been widely used in cementless press-fit hip components for many years, and using identical constituents, namely plasma sprayed titanium and hydroxyapatite. These materials have not been

used when sprayed directly onto ceramic before, and will be used for the first time in humans in this study.

If after your surgery there is a fracture of the bone, or fracture or loosening of the implant, you may require a further operation to resolve the issue. This may include a total hip replacement, fixation of the fractured bone with plates, wires or screws, or a hip resurfacing arthroplasty with a similar device.

In rare cases, ceramic bearing hip replacements have squeaked. This audible noise is not painful, but embarrassing. The audibility of the squeak depends upon the shape and stiffness of the metal stem in the femur. As the H1 does not have a long stem in the femur to oscillate, amplifying the sound, the risk of squeaking is reduced.

Tests like CT scans and hip x-rays will expose you to radiation which has the potential to cause cancers later in life. There are many natural sources of radiation in the environment that we are all exposed to throughout our lives. The additional radiation you would receive as part of this study is roughly equivalent 3 years and 4 months of this natural background radiation, spread over the 10 years of this study. The risk of radiation exposure adds up over a lifetime. If you have any concerns about this you can discuss them with your study doctor.

Whilst performing the gait assessment you may find that some of the tasks we ask you to perform cause you some discomfort, pain, or a feeling of instability. Should this happen simply inform the researcher and if you need to rest or want to stop, you can do so at any time. We will be attaching the microphones to your skin using adhesive tape, which may cause some temporary redness of the skin. If you have allergies or skin conditions (e.g. eczema, dermatitis, etc.), please inform the researcher and he or she will use an elastic material to protect your skin.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

You may benefit from the study by receiving the H1 implant, which is designed to address the symptoms associated with a degenerated hip. In addition, receiving this implant may reduce the amount of bone that must be removed. However, the device has not been studied clinically and so benefit is not assured. There are no other clear benefits to you from taking part. However, the information we get from this research might help in the future with management of joint disease. It also might help assess how well a certain intervention worked on an individual. We also expect that you will gain a strong sense of what you can and cannot do, if this was not already apparent to you.

If you have not yet had treatment, or if you have already been treated, this may help us all appreciate any limitations you experience.

WILL MY TAKING PART IN THIS STUDY BE KEPT CONFIDENTIAL?

Yes. Any information you give us and that we measure will be kept strictly confidential. If the study is published in a book or scientific journal, individuals will not be identified in any way. If you would like to receive the results of the study when completed, we are happy to send it to you electronically as an email or by Royal Mail. Please let us know at any point if you would like to receive this information.

Authorized personnel or designee of Embody Orthopaedic Limited, as the sponsor and its commercial partners, such as Zimmer Biomet, NHS or your local hospital, Imperial College London and regulatory authorities may have to look at the data to ensure the study is being conducted properly and meets the appropriate standards. The study data will be analysed at the coordinating site Imperial College London. Independent clinical evaluators may come to Imperial College London to analyse the combined results from all centres. All data will be encoded at point of consent. Your encoded data will be stored using a unique identification number to ensure patient confidentiality. Online questionnaires collected via JointPro are password protected and only the patient and his/her surgeon or investigator will have access to the data. The investigator or the named research team member at each site will have an account where they can export and electronically submit the encoded data to the coordinating site, Imperial College London.

All local sites will store the data until the completion of the 10 year follow up study. Following completion of the study, all encoded research source data will be stored with the coordinating site at Imperial College London for 10 years. In the event the study has to be revisited and patient identification is required we will request for permission to access identifiable data, which will be kept securely with Imperial College London. In order to contact you for follow up appointments, we will be storing your personal identifiable data on a secure MSK Imperial College London server that meets the college criteria for storing identifiable data. Once all follow up visits have been completed, your personal identifiable data will be deleted from the server. You have a right to seek access to your personal data at any time. You are also entitled to request that your personal data be corrected or erased in accordance with UK law and to object to the use of your personal data at any time. Please contact Imperial College London at m.al-laith@imperial.ac.uk if you have any questions about the use of your personal data or wish to exercise the rights provided in this paragraph. As part of this study, we will also notify your GP of your participation. If you are happy for us to do this, you will be required to sign a clause in the consent form.

Your encoded data (which will not include your name or date of birth) may also be shared with the manufacturers of the H1 HRA commercial partners such as Zimmer Biomet, as the study data may be used by the manufacturer to demonstrate the safety and efficacy of the implant to the regulatory authorities and receive a CE marking enabling them to distribute the implant. In the event of the occurrence of an adverse event, the person nominated by Embody Orthopaedic Limited may be provided access to the source data for the exclusive and limited purpose to permit investigation of the event in fulfilment of obligations provided in applicable laws.

Zimmer Biomet is based in the United States where national data protection laws do not provide the same level of data protection as do the laws of the United Kingdom. The encoded data that is shared with such commercial partner will not include your name or date of birth. This information will be kept in Imperial College. If you are happy for us to share your encoded data with the manufacturers, you will be asked to sign a clause in the consent form regarding sharing data with these third parties.

We use personally-identifiable information to conduct research to improve health and care. As a medical device company we have a legitimate interest in using information relating to your health and care for research studies, when you agree to take part in a research study. This means that we will use your data, collected in the course of a research study, in the ways needed to conduct and analyse the research study. Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter (Dr Susannah Clarke, susannah.clarke@embody-ortho.com). If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO).You can find out more about how we use your information [Mariam Al-Laith, email m.al-laith@imperial.ac.uk , Tel:020 7594 2697

WHAT IF SOMETHING GOES WRONG?

Embody Orthopaedic Limited holds insurance policies, which apply to this study. If you experience serious and enduring harm or injury as a result of taking part in this study, you may be eligible to claim compensation without having to prove that Embody Orthopaedic Limited is at fault. This does not affect your legal rights to seek compensation. If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the local investigator Professor Justin Cobb, email: j.cobb@imperial.ac.uk. The normal National Health Service complaints mechanisms are also available to you.

For independent advice about participating within a research study, please contact the patient advice and liaison service (PALS) based at Charing Cross Hospital, Fulham Place Road, London W6 8RF (Tel: 020 3313 0088).

WHO IS ORGANISING AND FUNDING THE RESEARCH?

This research is being funded by Embody Orthopaedic Limited, the manufacturer of the H1 HRA. The study has been organised and will be run by a research team based at Imperial College London, although your assessments and surgery may be performed in the hospital you were referred to by your GP. The Chief investigator (CI)/Principal Investigator (PI) named in this application has helped develop and manufacture the H1 hip resurfacing device and as such there is a potential for financial gain for the CI/PI and Imperial College London from the success of this study. The intellectual property generated from this study will rest with Embody Orthopaedic Limited.

WHO HAS REVIEWED THE PLAN FOR STUDY PLAN?

This study has been approved by The Medicines and Healthcare products Agency (MHRA), East of England – Cambridge Central Research Ethic Committee (REC) and Health Research Authority for NHS approval.

CONTACTS FOR FURTHER INFORMATION

If you have further questions or require further information please do not hesitate to contact the Chief Investigator, Professor Justin Cobb via the Research Team Assistant Jurgen Pasha:

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GLOSSARY

Arthritis	A disease causing painful inflammation and stiffness of the joints
Arthroplasty	The surgical reconstruction or replacement of a joint
CE mark	A symbol applied to products to indicate that they conform with relevant EU directives regarding health and safety or environmental protection
Gait	A person's manner of walking
H1 HRA	H1 Hip Resurfacing Arthroplasty - the device being used in this study
HRA	Hip resurfacing arthroplasty - replacement of the surfaces of the hip joint
MHRA	Medicines & Healthcare products Regulatory Agency The Medicines and Healthcare products Regulatory Agency regulates medicines, medical devices and blood components for transfusion in the UK. MHRA is an executive agency, sponsored by the Department of Health.
NHS	National Health Service
THA	Total hip arthroplasty - complete replacement of the hip joint