Division of Surgery
Department of Surgery and Cancer
Imperial College London

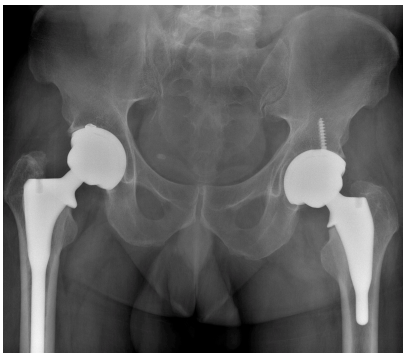
King Edward VII's hospital Sister Agnes
Beaumont Street
London W1G 6AA
Tel: 0207 224 0326

Chief Investigator: Professor Justin Cobb

Furlong Evolution® Hip Trial

Patient Information Sheet

Version 2 28/06/2012



Invitation

We would like to invite you to take part in our research study involving a new hip replacement 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 (*Mathew.furtado@imperial.nhs.uk*) 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 function and survival of the new Evolution® hip replacement implant, which was CE marked in October 2011. As part of on going developments in hip replacement implants, this new modification has been developed from an existing hip replacement stem, which has very good long term results. The reason for the development was to try to give the patient a better surgical and rehabilitation experience with a much kinder operation. In theory this new hip stem might aid post operative recovery and may also perform at least as good as its predecessor. We must stress that the benefits and potential downside of the Furlong Evolution® Hip Stem is currently not known and is being evaluated in this study.

We wish to test these potential benefits by making a long term commitment to follow patients who consent to the new Furlong Evolution® 10 years after operation.

Why have I been Invited?

You are someone who has had problems with your hip and have been deemed a suitable person to have a hip replacement.

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. Unfortunately travel costs will not be provided for this trial.

What will happen to me if I take part?

Once you have decided to take part in this research, you will be contacted to come to a pre-assessment clinic as per normal routine practice. Here you will be given the date of surgery. This process will be the same whether you decide to take part or not. You will also as routine practice have an x-ray at pre-op and post-op and at 6 weeks post-op. If you decide to take part in this research you will have additional 6 sets of x-rays, one set at each additional follow-up visit.

This is a 10 year surveillance study, which will include follow-up visits at (insert hospital name), 6weeks, 6months, 1year, 3years, 5years, 7years and 10years following surgery. At these appointments you will fill questionnaires to gage how you are doing as well as having a clinical examination. X-rays will also be taken. At these additional follow-up visits you may also be offered to come to the Biodynamics Laboratory (*Charing Cross Hospital*) for a gait assessment on a treadmill.

Treadmill Gait Assessment (Available at Charing Cross Hospital)

You will be offered to attend 7 sessions (Pre-op and post-op at 6months, 1year, 3years, 5years, 7years and 10years) in the Biodynamics Laboratory, lasting about 1hr each time. This assessment is only available in Charing Cross Hospital, although patients from other centres will be given the option to attend. If attending, we will place you on a commercially modified treadmill and ask you to carry out several tasks, which include walking on flat ground, and walking both uphill and downhill. We will modify the speed and the slope of the treadmill within the limits of comfort, to assess what you feel comfortable with. Please note this part of the research is entirely optional and are not obliged to carry out this part of the assessment.

N.B. You will need to bring a pair of comfortable walking shoes during the assessment.

Prior to surgery will also be asked to complete some questionnaires that will assess your hip joint function and pain, your physical activity levels and activity aspirations. The questionnaires should take no longer than 20 minutes to complete. Again you will be asked to complete these whether you take part or not.

What are the side effects, and are there any risks in taking part?

If performing the walking assessment you may find that some of the tasks we ask you to perform cause you some discomfort, pain or feeling a sense of instability. Should this happen, please inform the researcher, and if you need to rest or want to stop, you can do so at any time. We do not want to cause you any pain, but do want to understand the limits of comfortable function for you at this particular time in your journey. The treadmill is fitted with hand rails, harness, "stop" cord, and an emergency stop button for your safety and to prevent any accidents from occurring. Additional X-ray examinations as part of the study will mean additional exposure to radiation. However there is a small amount of radiation dose associated with the X-Rays. The dose from each pair of x-rays is approximately equivalent to 4 months background radiation and carries a minimal risk.

What are the possible benefits of taking part?

There are no 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. It may also help in the assessment of a patient rehabilitation process. 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. The new implant would certainly have the benefit of being a much more conservative implant by preserving much more of patients own bone stock.

Will my taking part in this study be kept confidential?

Any information you give us will be kept strictly confidential. If the study is published in a book or scientific journal, no individual will be identified in anyway. Imperial College Healthcare NHS Trust / Imperial College and regulatory authorities may have to look at the data to ensure the study is being conducted properly and meets the appropriate regulations.

What if something goes wrong?

Imperial College London 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 Imperial College 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 Clinical trial coordinator Mathew Furtado on 02033117326. The normal National Health Service complaint complaints mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial AHSC Joint Research Compliance Office".

Patients who have private medical insurance are advised to inform their insurance company of their participation in the study.

What will happen to the results of the research study?

The results of the study will be analysed by the research team and presented at conferences and published in scientific journals. No individual subject will be identified in any report or presentation arising from the research. 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 for this information.

Who is organising and funding the research?

This research is being part funded by Joint Replacement Instruments ltd (JRI). The study 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 you general practitioner.

Who has reviewed the study?

This study has been submitted to Research Ethic Committee (London-Westminster) and reviewed by Imperial College Joint Research Compliance Office.

Contacts for further information:

If you have further questions or require further information please do not hesitate to contact co-investigator Mathew Furtado

Telephone: 020 331 17326
Email address: Mathew.Furtado@imperial.nhs.uk