IRAS Project ID: **339982**

Post-market clinical follow-up study for Zimmer femoral nails - Participant Information Sheet

Before you decide whether to take part or not, you need to understand why the research is being done and what taking part would involve for you. Taking part is voluntary. If you choose not to take part, you do not have to give any reason and the quality of your care will not be affected.

Please take time to read the following information carefully. A doctor will phone you from the phone number 01233 63331 in about 3-4 weeks and will go through this information sheet with you, to help you decide whether or not you would like to take part and answer any questions you may have. Talk to others about the study if you wish, such as friends or family and take your time to decide.

Why are we doing this research?
As per government guidelines, once a medical device, has been placed on the UK market, post-marketing surveillance must be performed mandatorily. Post marketing surveillance is a set of activities conducted by manufacturers, to collect and evaluate experience gained from medical devices that have been placed on the market, and to identify the need to take any action. This post-marketing surveillance will review the femoral nail used to treat the femur (thigh bone) fracture sustained by you.

What is the purpose of this study?
Post-market surveillance is a crucial tool to ensure that medical devices continue to be safe and well-performing and to ensure actions are undertaken if the risk of continued use of the medical device outweighs the benefit. The evaluation of post-market surveillance experiences can also highlight opportunities to improve the medical device. This study aims to assess safety and performance of the medical device used for you, i.e., femoral nail.

Who is undertaking the study?
This study is being undertaken by researchers at East Kent Hospitals University Foundation Trust, who are the sponsors for this study. The East Kent Hospitals Trust includes William Harvey Hospital and Queen Elizabeth the Queen Mother Hospital.

Who is being included in the study?
Patients who sustained thigh bone (femur) fractures and underwent surgery with implantation of medical device (femoral nail) will be included in the study. We are contacting you as you underwent implantation of a femoral nail for a femur fracture.

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What happens next if I agree to be included in this study?
You will receive a phone call from a doctor who will answer your queries regarding the study and confirm if you want to participate in the study. If you agree to be included in this study, we will record your verbal consent. We will review your medical records and collect data regarding treatment including your age at the time of the operation, sex, weight, height, other medical problems if any, injury sustained, surgery you underwent, information about the medical device (nail) used, the time it took for the fracture to heal and any complications sustained during the course of treatment. Additionally, the doctor will also conduct a telephone interview and ask you a few questions regarding pain and functional performance following surgery. Pain will be assessed by using a questionnaire called the visual analogue scale to assess pain level and functional performance following surgery will be assessed by using a questionnaire called the Oxford Hip Score/ Oxford Knee Score. The telephone interview should take about 10 minutes to complete. If any incidental issues are identified during the telephone interview, we will advise you to contact your GP for an assessment.

What are the possible risks and benefits of being in the study?
There are no risks to being included in the study. Your participation in the study could confirm the safety and utility of the medical device. Information collected about the medical device will be shared with the manufacturer. All information shared will be anonymised. Additionally, your participation could also help in development and improvement of the medical device.

Can I stop the study treatment or my participation early?

- Yes. You have the right to withdraw at any time without reason and this will not affect your current or future medical care. If you wish to withdraw from the study please call 01233 633331 and ask for extension 7236723 to express your withdrawal from the study to the doctor conducting the study.

How will we use information about you?

We will need to use information from you for this research project.

This information will include your age at the time of the operation, sex, weight, height, other medical problems if any, injury sustained, surgery you underwent, information about the medical device (nail) used, the time it took for the fracture to heal and any complications sustained during the course of treatment. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

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Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

Will my participation be kept confidential and how will my data be managed and stored?

If you decide to take part in this study, all information about you will be kept strictly confidential. All personal details will be removed before analysing and presenting the data. All information including your initials, date of birth, contact details and NHS number, will be stored securely for a maximum of 5 years. Some parts of your medical records and the data collected for the study may be looked at by authorised persons from the East Kent Hospitals University Foundation Trust. Data may also be looked at by representatives of regulatory authorities and by authorised people from other NHS bodies to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- 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.

Where can you find out more about how your information is used?
You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- the leaflet available from [www.hra.nhs.uk/patientdataandresearch]
- by ringing us on 01233 633331 and ask for extension 7236723

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the normal NHS Complaints Procedure. Please contact the Patient Advice and Liaison Services (PALS) team at your hospital on: 01227 783145 or 01227 864314

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed and this is due to someone's negligence, then you may have grounds for a legal action for compensation against the NHS Trust where you are being treated, but you may have to pay for your legal costs. The normal National Health Service complaints mechanisms should be available to you (if appropriate).

In the event of a defective product, then you may have grounds for a legal action for compensation against the manufacturer, but you may have to pay for your legal costs.

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Are there any financial costs or payments?
No there are no financial costs or payments for taking part in this study.

Who has reviewed the study?
This study was reviewed and approved by our local research and development office, the Health Research Authority and Regulatory Ethics Board.

Thank you for taking the time to read this leaflet. If you have any questions about this study or would like to speak with a member of the research team contact 01233 633331 and ask for extension 7236723.