

Investigating Fracture and Osteoporosis

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Patient Information Sheet

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Introduction

We would like to invite you to take part in our research project. It is important that you know what is being done and why, so you can decide if you wish to be involved. Please take time to read and understand this information, talking to others if you wish, before deciding if you would like to take part. A researcher will go through the information sheet with you and you will have a chance to ask any questions before choosing to take part or not.

It is also important that you understand that you do not have to take part in this research. You are free to decline to enter or withdraw from the study at any time without giving a reason. This will not alter the standard of medical care that you receive.

Part 1 will tell you the study's purpose and what it will involve if you choose to take part. Part 2 gives you more detailed information about the conduct of the study.

Part 1 – why and what

Why is the research being done?

This research aims to test **new methods for diagnosing osteoporosis** and to increase the understanding of the disease. Osteoporosis is a bone disease that reduces the quality of bone, making it more likely to fracture. This **affects around 3 million people in the UK** leading to **230 000 fractures per year**. Patients who have had a hip replacement due to a fractured hip bone are being invited to join this study.

The study is being undertaken at University Hospital Southampton and the University of Southampton as part of a postgraduate project.

What does the research involve for me?

After you have had time to read this information you will be contacted by a researcher who will ask if you would like to take part. **Remember, you are free to say no or change your mind**. If you agree to take part you will be asked to sign a consent form. You will be given a copy of the form and a copy will be stored with your medical records and sent to your GP. The form asks for permission for us to:

- **Use bone** that has been removed as part of your hip operation.
- **Take blood and urine** samples to investigate factors relating to your osteoporosis and hip fracture (including genetic studies); these will not identify any individual genetic abnormalities or diseases.
- **Use information** from your medical records and to collect further information about you. This includes some blood test results and information on fracture risk factors and history.
- **Have bone density scans** (DEXA and pQCT scans).

For the bone density scan (DEXA and pQCT scans), you will be asked to return to the Southampton General Hospital approximately 1 month after you are discharged. You will be contacted to arrange the time and date of the appointment which will last less than 1 hour.

Are there any risks or benefits in taking part?

This study has **no major risks** for you. We will only use the bone that was removed for your operation: no additional bone is taken. Blood and urine samples are typically taken as part of your standard care. The DEXA and pQCT scans to measure your bone density will expose you to a very low dose of x-rays, similar to the level you would experience outside in a week.

There is **likely to be no direct benefit** for being part of this research. However, **this research aims to help patients with osteoporosis** in the future. We will put these research findings onto the website (www.soton.ac.uk/osteo) but they will be completely anonymous. The DEXA scan results will be available to your care team and GP (with your permission) and may help them with your treatment. You are asked to donate your tissue and be part of this research freely and will not receive any financial reward now or in the future. However, we do not want you to be out of pocket and can provide up to £20 toward travel if you need us to. To claim this, please bring travel receipts to the assessment session if possible.

Part 2 – detailed information

Is this confidential?

Any **personal information** that could identify you, such as name, contact details or NHS number will **only be stored on NHS computers**, being **strictly confidential**. All information stored outside of the hospital (i.e. at the University of Southampton) will be anonymous and the link to personal information will be coded. **All information will be stored securely and in accordance with the Data Protection Act.**

We will present the results at scientific meeting, publish them in journals and display them on the website (www.soton.ac.uk/osteo) to allow others to learn from our research but all results will be completely anonymous.

What will you do with the samples I donate?

The **bone samples will be tested at the University of Southampton to investigate new tools for diagnosing osteoporosis** and increase understanding of the disease. The bone tissue will be stored at the University for the length of the research. If any tissue remains at the end of this research, with your permission, the samples may be used for other research projects that have ethics approval. It is not yet known what these research projects involve.

What if something goes wrong?

We do not believe that there is any risk to you by taking part in this research. However, **if something does go wrong** due to someone's negligence, then **you may have grounds for legal action for compensation against University Hospital Southampton or the University of Southampton**. The normal NHS complaints system is also available to you and any complaint will be addressed.

Please initially raise your concerns with the Chief Investigator, Dr Philipp Thurner. If you wish to make a more formal complaint, please contact the hospital's Patient Advice and Liaison Service (PALS). Tel: 023 8079 8498, email: PALS@uhs.nhs.uk, write: PALS, C Level, Centre Block, University Hospital Southampton, Tremona Road, Southampton, SO16 6YD.

Who is involved with the research?

The research is being undertaken by students and staff at the University of Southampton but working with staff as University Hospital Southampton. This study is part of a Doctoral degree project at the University of Southampton for Tom Jenkins, supervised by Dr Philipp Thurner and Dr Nick Harvey and working with postdoctoral research fellow, Dr Louise Coutts. Dr Nicole Moss, a registrar at University Hospital Southampton, will also be undertaking the research.

The research is being funded by the Engineering and Physical Sciences Research Council (EPSRC). This study has been reviewed and approved by the National Research Ethics Service (NRES).

Research Team Contacts

Please contact us with questions, complaints or if you wish to withdraw from the research.

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