

Participant Information Sheet for Healthcare Research

Pain generators in osteoporosis induced insufficiency fractures of the spine
(Causes of pain in those with fractures of the spine due to osteoporosis)
principal investigator Dr David Wilson

Invitation

You are being invited to take part in a research study. 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.

Part 1 tells you the purpose of this study and what will happen to you if you take part.
Part 2 gives you more detailed information about the conduct of the study.

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.

Thank you for reading this.

The purpose of this study

Osteoporosis is a very common disorder affecting a substantial proportion of the older population. All humans lose bone mineral from the peak aged 20 years at a rate of approximately 1% per year. When bone mineral density is approximately 25% of the level it was in youth then spontaneous fractures may occur during normal everyday activities.

It is estimated that there are 120,000 symptomatic osteoporotic insufficiency fractures in the UK every year based on North American data. Research in Canada suggests that 25% of the total population over the age of 55 have silent insufficiency fractures which they may only find out about by accident, for example if they have a chest x-ray for other reasons.

We do not know why some people have severe pain following a fracture of the vertebral body in the spine and why some have absolutely no symptoms.

This study is part of research to investigate the causes of pain from spine fractures due to osteoporosis. Dr Wilson is a senior spine radiologist in Oxford who has been treating spine insufficiency fractures since 1990. He is undertaking this research as part of his thesis to be submitted for a doctorate in medicine at Imperial College London.

Why you have been invited?

It is difficult to identify those who had fractures of the spine without any symptoms. We are asking anyone who knows they have had a fracture whether painful or not to complete an anonymous questionnaire to provide us with more information.

Our research question is “What is the difference between symptomatic and asymptomatic insufficiency fractures of the spine caused by osteoporosis?”

Do you have to take part?

Completing this questionnaire is entirely voluntary. It is up to you to decide whether or not to take part. At the beginning of the questionnaire, we will ask whether you give consent for the data to be used for scientific research. If you decide to take part, you are still free to withdraw at any time and without giving a reason. Any data that you enter will not be saved if you do not click the submit button at the end of the questionnaire. Because we are not recording any personally identifiable information we would not be able to identify and remove your individual information if you change your mind after submitting your response.

What will happen to you if you take part?

Once you have decided to take part in this study, access participant information sheet. If at this point you have any questions Dr David Wilson (email: info@slro.co.uk Tel: 01865 742949) will be happy to discuss the study with you and answer any questions you may have. If you are still happy to take part, we will ask you to complete an online consent questions first before the questionnaire that will take between 15 and 30 minutes.

Once the survey is completed, we will not need to contact you again for information and indeed would not have your name or details in any of the records.

What are the possible disadvantages or risks to you by taking part?

We do not believe that harm is likely to result from completing a questionnaire however we are aware that medical matters may create concerns or anxiety. We are always available to explain the study further or deal with other related matters if you wish.

What are the possible benefits to you taking part?

We do not believe that the study can benefit you individually, but we hope it will advance the understanding of the disease and improve future management and treatment for everyone with osteoporosis and spinal fractures.

What if something goes wrong?

If you have any complaints or concerns, please feel free to contact the principal investigator Dr David Wilson or the sponsor Imperial College London.

If you are harmed by taking part in this research project, there are no special compensation arrangements. 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 Investigator Dr David Wilson contact details below. If you are still not satisfied with the response, you may contact Research Governance and Integrity Team (RGIT).

What will happen to the results of the research study?

The findings of this study will be published in a peer-reviewed scientific journal and as part of Dr Wilson's thesis.

As we are not collecting any information about you that could identify you and we will not have any contact details we suggest that you might like to look at our website www.stlukesradiology.org.uk in the later part of 2021 as we will publish the outcome of our survey for anyone to read.

Who is organising and funding the research?

Dr Wilson is organising the study and funding this research himself out of income from medical practice.

Who has approved the study?

This study was given ethical approval by Professor Justin Cobb Head of Department and Research Governance and Integrity Team (RGIT).

Contact for Further Information

if you have any concerns or require further information please contact Dr Wilson via his medical practice in Oxford (01865) 742949, info@slro.co.uk.

Please keep a copy of this form if you wish.

Thank you very much for reading this information and of course thank you again if you decide to complete the questionnaire.

TRANSPARENCY NOTICE

In this research study we will use information from you. We will only use information that we need for the research study. We will not ask for your name or any contact details.

Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.

At the end of the study we will save some of the data for future research.

There will be no means by which anyone can know that you provided this information and we will hold no names or contact details

HOW WILL WE USE INFORMATION ABOUT YOU?

Research Study Title: Pain generators in osteoporosis induced insufficiency fractures of the spine

[ICREC number 20IC6271]

Imperial College London is the sponsor for this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Imperial College London will keep your personal data for:

- 10 years after the study has finished in relation to data subject consent forms.
- 10 years after the study has completed in relation to primary research data.

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

This information will not include your name or contact details indeed we will not ask for or hold this data. People will use this information to do the research or to that the research is being done properly.

We will keep all information about you safe and secure.

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.

You can find out more about how we use your information by ringing us on (01865) 742949 or sending an email to info@slro.co.uk

LEGAL BASIS

As a university we use personally identifiable information to conduct research to improve healthcare and services. As a publicly funded organisation, we must ensure that it is in the public interest when we use personally identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study.

Health and care research should serve the public interest, which means that we must demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research

INTERNATIONAL TRANSFERS

There may be a requirement to transfer information to countries outside the European Economic Area (for example, to a research partner). Where this information contains your personal data, Imperial College London will ensure that it is transferred in accordance with data protection legislation. If the data is transferred to a country which is not subject to a European Commission (EC) adequacy decision in respect of its data protection standards, Imperial College London will enter into a data sharing agreement with the recipient organisation that incorporates EC approved standard contractual clauses that safeguard how your personal data is processed.

SHARING YOUR INFORMATION WITH OTHERS

For the purposes referred to in this privacy notice and relying on the bases for processing as set out above, we will share your personal data with certain third parties.

- Other College employees, agents, contractors, and service providers (for example, suppliers of printing and mailing services, email communication services or web services, or suppliers who help us carry out any of the activities described above). Our third-party service providers are required to enter into data processing agreements with us. We only permit them to process your personal data for specified purposes and in accordance with our policies.
- the following Research Collaborators / Partners in the study :-
 - Third Party University – explain what data and why it will be shared
 - Third Party Company – explain what data and why it will be shared
 - Third Party Government department – explain what data and why it will be shared

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.

- **OPTION if follow up data will be collected after withdrawal:** If you choose to stop taking part in the study, we would like to continue collecting information about you from [give details] If you do not want this to happen, tell us and we will stop.
- 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

- by asking one of the research team
- by sending an email to info@slro.co.uk , or
- by ringing us on 01865 742949

COMPLAINTS

If you wish to raise a complaint on how we have handled your personal data, please contact Imperial College London's Data Protection Officer via email at dpo@imperial.ac.uk, via telephone on 020 7594 3502 and/or via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

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). The ICO does recommend that you seek to resolve matters with the data controller (us) first before involving the regulator.