Participant Information sheet for people who have experienced pregnancy associated osteoporosis

You are being invited to take part in a research study which aims to gather information on the causes and health impact of pregnancy associated osteoporosis from people who are resident in the UK. To help you decide whether or not to take part, 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. Talk to others about the study if you wish. Contact 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 this study?

The purpose of the study is to gain greater understanding of what causes pregnancy associated osteoporosis (PAO). This is a rare condition that is associated with the development of fractures (broken bones) during pregnancy or lactation. The cause of PAO is not well understood. The purpose of this study is to document the characteristics of women who have been diagnosed with PAO and to compare a control group of women who were not diagnosed with PAO during pregnancy or lactation.

There are two parts of this study. In the first part you will be asked to complete an anonymous survey. At the end of this survey there will be an option to provide contact details so that we can get in touch with you and get more information about the tests you had at the time of the diagnosis either from your GP or hospital consultant and obtain a blood sample. The blood sample will normally be taken by a member of the clinical team at the hospital responsible for your clinical care at the present time. In the event that you are not currently attending a hospital for clinical care the blood sample will be taken by research staff at one of the many centres across the UK that are taking part in the study.

Would my travel expenses be reimbursed?

Yes. We would be very happy to reimburse travel expenses if you require those to get to the hospital for blood samples to be taken. If you wish to claim travel expenses, please contact a member of your local study team or the co-ordinating centre for details on how to go about this.

Why have I been invited to take part?

You have been asked to take part as you have been diagnosed with Pregnancy Associated Osteoporosis.

Do I have to take part?

No, it is up to you to decide whether or not to take part. If you do decide to take part, you may download this information sheet to keep and complete an online consent form. If you enrol into the study, you are still free to withdraw at any time and without giving a reason. Deciding not to take part or withdrawing from the study will not affect the healthcare that you receive, or your legal rights.

What will happen if I take part?

The study has two parts. This section describes what will happen in each of them

In the first phase (Phase I), you will be asked to complete a web-based questionnaire which should take around 20 minutes. This will ask you some questions about your diagnosis, your general health and your quality of life. This information will be collected anonymously, and you will not be asked for

any personal information about yourself. At the end of the first part of the study you will be given the option of consenting to take part in the second phase of the study.

The second phase of the study (Phase II) will involve you agreeing to provide us with your contact details (name, date of birth, email address, home address and telephone number) and contact details of your normal healthcare providers (GP and hospital consultant). The reason for this is that we want to gather detailed information on the results of any tests that were performed at the time of your diagnosis with PAO and also details of any fractures you may have suffered. In addition, we would like you to provide a blood sample which will be used for genetic analysis and biochemical analysis, to find out more about the causes of PAO. Providing a blood sample is optional. You can still take part in Phase II without providing a blood sample. Participation in Phase II of the study is only possible if you are a UK resident.

As part of the study, we want to be able to compare the characteristics of women who have been diagnosed with PAO with those who have gone through a pregnancy and not been affected with PAO. We would therefore like you to nominate a friend or acquaintance about the same age as you who had a pregnancy around the same time as you but were not affected by PAO. You can still take part in the study without doing this and there is no obligation to nominate a control. If you wish to nominate a control and they agree to take part we will send you a link to the control questionnaire so that you can pass that onto them for completion.

What will happen with the blood samples?

If you provide a blood sample, genetic studies will be performed to try and determine if this may be a factor involved in causing PAO. The genetic analysis may include the use of techniques called whole genome analysis or exome analysis in which we can comprehensively search for genetic variants that predispose to PAO and the evaluation of changes that result in modification of gene expression rather than alteration of the genetic code itself. This is sometimes referred to as epigenetic analysis. The blood samples will also be used to determine if there are any changes in bone metabolism by analysing what is termed “biochemical markers” of bone turnover. This can give an insight into the rate at which the skeleton is being repaired and renewed. The genetic analysis and biochemical analysis are being performed purely for the purposes of research to find out more about PAO and the tests performed are not expected to reveal results that require any treatment or further tests.

Is there anything I need to do or avoid?

No, not particularly. There isn’t anything special that you need to do or avoid if you take part in the study.

What are the possible benefits of taking part?

There are no direct benefits to you taking part in this study, but the results from this study might help to improve the healthcare of PAO patients in the future and will help increase understanding of the causes of PAO.

What are the possible disadvantages of taking part?

You might experience some mild discomfort as the blood sample is taken, if you consent to taking part in the second stage of this study.

What if there are any problems?

If you have a concern about any aspect of this study, please contact Dr Adrian Tan who will do their best to answer your questions.

In the unlikely event that something goes wrong, and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against NHS Lothian, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

What if I decide I want to withdraw from the study?

You are free to withdraw from the study at any time. If you decide to withdraw you don't have to give us a reason why, and your decision to withdraw will not affect the standard of medical care that you receive. If you withdraw from the study, we will keep the information about you that we have already obtained, unless you specifically request that this is destroyed. If we have not yet analysed your study samples, you can request that we destroy these.

What happens when the study is finished?

We plan to keep records of your personal details, the samples you have provided and the data that we have gathered about you during the study for 15 years. We will also invite you to consent to being contacting about future studies on PAO that may be of interest to you once this study is completed.

Will my taking part be kept confidential?

Yes. All the information we collect during the course of the research will be kept confidential and will only be seen by members of the study team who are concerned with analysis of the study date. The study will adhere to the laws which safeguard your privacy at every stage.

How will we use information about you?

Your privacy is important to us. If you consent to taking part in Phase I of the study, we won't store any personally identifiable information about you, but we will store and use the data you have provided to gain a better insight into why PAO occurs

If you consent to taking part in phase II of this study, we will be asking you to consent to you providing your name and contact details as well as the details of your GP and hospital consultant. This information will be used to contact your healthcare provider for details of the tests that were done at the time of the diagnosis of PAO and the sites of any broken bones you had as well as details of your general health and any medication you may have been taking. We will also ask for details about your bone health currently. The information about you will be held in a secure database to which only authorised members of the study team have access. Your contact details are only being held for administrative purposes and your personal details will not appear in any report of publication describing the results of the study. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- 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. However, you can stop taking part in the study at any time without giving a reason and if you request it, we will delete the personal information we have about you. If you have provided non-personal information about the study (such as filling in the web-based questionnaire) we will keep that information provided it was gathered before you decided to withdraw from the study

Where can I find out more about how your information is used?

You can find out more about how we use your information through the following sources

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from [**www.hra.nhs.uk/patientdataandresearch**
- by asking one of the research team
- by sending an email to Kathryn.Berg@igmm.ed.ac.uk, or
- by ringing us on 0131 651 8726.

What will happen to the results of the study?

We plan to publish the results of the study when all of the data have been analysed. This will be done by presentations at conferences and through publications in scientific journals. You will not be identifiable in any presentations or scientific papers that are published as the result of the study. We are also planning to make the results of the study available to people who took part in the study. Various means may be used to do this such as email, or a newsletter which we can send you if you wish.

Who is organising and funding the research?

This study has been organised by the University of Edinburgh and is jointly sponsored by the University of Edinburgh and NHS Lothian. The study is being funded by the Royal Osteoporosis Society.

Who has reviewed the study?

The study has been reviewed by clinicians, scientists and lay members of the Royal Osteoporosis Society - a patient support organisation. The study has also been evaluated and approved by a research ethics committee. All research in the NHS is looked at by an independent group of people called a Research Ethics Committee. A favourable ethical opinion has been obtained from the London Riverside Research Ethics Committee. NHS Management Approval has also been given.

Researcher Contact Details

If you have any further questions about the study, please contact Professor Stuart Ralston on 0131-651-8741 or email on: stuart.ralston@ed.ac.uk.

Independent Contact Details

If you would like to discuss this study with someone independent of the study, please contact Dr Adrian Tan by emailing: adrian.tan@nhsborders.scot.nhs.uk. You may also write to Dr Tan at: Rheumatology Department, Borders General Hospital, Melrose, TD6 9BS.

Complaints

If you wish to make a complaint about any aspect of the study, please contact:
Patient Experience team, NHS Lothian, 2nd Floor
Waverley Gate, 2-4 Waterloo Place
Edinburgh EH1 3EG
Tel: 0131-536-3370
Email: feedback@nhslothian.scot.nhs.uk