Patient information sheet

Developing Core Outcome sets in Female Idiopathic Chronic Pelvic Pain

(Study Number: 277330)

We would like to invite you to take part in our research study. Participation is entirely voluntary. Before you decide whether to take part in the study, we would like you to understand why the research is being done and what it would involve for you.

On the day of your appointment, one of our team will meet you to talk in more detail and answer any questions you may have. We anticipate this should take about 10 minutes. Please feel free to talk to others about the study if you wish.

Chief Investigator:

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What is the purpose of the study?

This study is to find out what you think the priorities in research for chronic pelvic pain should be. By involving patients such as yourself we can ensure your views are represented in future research.

Why have I been chosen?

We are inviting all women over the age of 18 who are attending our clinic with chronic pelvic pain.

Do I have to take part?

It is up to you whether you to choose to take part in the study. If you choose to take part you will be given this information sheet for your records and asked to sign a consent form. You can refuse to take part and this will not affect the care you receive.

What will happen to me if I take part?

If you agree to take part in the study, you will be asked to register on our webpage and asked for an email address. This is so we can contact you with instructions to complete the survey. There will be two surveys which can be completed online. These will take 30 to 60 minutes each.

You will be also invited to attend a meeting at the end of our study. This is to discuss the results of the study. This meeting will be for half a day. The meeting can be joined by teleconference.

What are the possible risks of taking part?

There are no risks associated with taking part in the study. However, to minimise inconvenience to you, surveys can be completed online over two weeks. You do not need to attend the meeting in person and can instead join it by teleconferencing.

What are the possible benefits of taking part?

There is no direct benefit to you from taking part in the study. However, findings from this study can be used to improve the care of women with chronic pelvic pain.

Will I be informed of the results?

Yes, we will provide a short summary and write our reports in a way that no-one can work out that you took part in the study.

Can I opt out after agreeing to take part in the study?

You can withdraw at any time without giving a reason but we will keep the information we have already about you.

How will we use information about you?

We will need to use information about you for this project. This will include your email address, name, age, gender and survey responses. People will use these details to do the research or 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 see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure. 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. Once we have finished the study, we will keep personally identifiable data so we can check the results for 12 months. We will not inform your GP that you have taken part in the study as we are not changing your care.

The Sponsor has contracted the services of the University of Liverpool to deliver the survey. The survey will collect personal information such as your name, age, gender and email address which will be held by the University of Liverpool in a secure database. This data will be held for 3 months after the study ends and then destroyed. If you wish to request your personal identifiable data is removed from the University of Liverpool database please contact the Chief Investigator.

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

You can find out more about how we use your information:

- On www.hra.nhs.uk/information-about-patients/
- By asking one of our research team: Miss Vishalli Ghai, vishallighai@nhs.net

What if something goes wrong?

Please speak to a member of the research team if you have if you have any concerns about this study. We will do our best to answer your questions. If you are still unhappy and want to make a formal complaint, you may do this through the independent hospital Patient Advice and Liaison Service (PALS). (Contact: 01372 735 243; Mon-Fri 0930 -1530).

What will happen to any feedback I give?

We value any feedback on our study that will be used to further improve our research process.

Who is organising this study?

Epsom and St. Helier Hospitals NHS Trust are funding and organising this study. As part of the study, we have established an international steering group. This group has doctors, nurses and researchers as well as women who have chronic pelvic pain. The purpose of this steering group is to help develop and guide the study.

Who is funding this study?

This project has been supported by a financial grant from Bayer Plc. Bayer Plc has had no involvement whatsoever in the development or implementation of the project.

Who has reviewed the study?

This study proposal was submitted online to Health Research Authority and has been reviewed by a Research Ethics committee.

Contact for Further Information

For any further information please contact:

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Thank you for considering taking part in this study.