GaPP2: A multi-centre randomised controlled trial of the efficacy and mechanism of action of gabapentin for the management of chronic pelvic pain in women.

Sub study: The effects of gabapentin on central pain processing in women with chronic pelvic pain of unknown cause

You have been invited to take part in this further study because you are taking part in the GaPP2 clinical trial. Before you decide whether you wish 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 leaflet carefully. Ask us if there is anything that is not clear or if you would like more information. Please take time to decide whether or not you wish to take part.

What is the purpose of this study?

You have agreed to take part in the GaPP2 clinical trial looking at the effectiveness of using gabapentin in the treatment of chronic pelvic pain. We know that gabapentin is helpful for other chronic pain conditions but we do not know how it works. We hope to improve our understanding of how gabapentin works by carrying out two MRI scans

of your brain whilst you are taking part in the main clinical trial. You will have one scan at the beginning of the study (before taking any medication) and one after you have been taking the medication for around three months.

What is an MRI scan?

An MRI (magnetic resonance imaging) scan is a way of using a magnetic field, radiowaves and computers to produce picture 'slices' of the human body. It does not use any forms of x-rays and has no known side effects. Some people find the scan uncomfortable (because they have to keep still in the scanner for a long time) or claustrophobic (nervous in small places). Such feelings will go away as soon as you are outside the scanner. If you know that you are claustrophobic you may wish to discuss this with the researcher beforehand. If you decide to participate, the researcher will check with you regularly during the scan to make sure you are comfortable. If you feel uncomfortable at any time, even after the scan has started you can inform the researcher and be quickly removed from the scanner. You do not have to go into the scanner again if you do not want to. There are no after effects of having a scan, so you are free to leave the scan centre when the scan is finished. It is safe to drive after an MRI scan.

Do I have to take part?

No. It is up to you to decide whether or not you wish to take part in the MRI part of the study. This will not affect your care in any way and you can still continue in the GaPP2 clinical trial.

What will happen to me if I take part?

You will be asked to sign a consent form and we will go through a checklist to make sure it is safe for you to have an MRI scan.

You will then be asked to attend an appointment at the Clinical Research Imaging Centre (CRIC) (image 1) in the Queen's Medical Research Institute at the Royal Infirmary of Edinburgh.

When you come to the CRIC for your scan, you will be asked to place any metal objects, such as jewellery, including body piercings, keys, watches, coins and credit cards, in a locker. Please do not wear any make-up or talc, and you may have to remove contact lenses if you use them. Please be aware that you must change out of clothing that contains metal, such as zips, and bras. You will be asked to change into a hospital gown. The scanning room is air conditioned, so it is recommended that you bring a jumper or cardigan (not containing any metal) and socks. There will be a private changing room for you to change in, and secure lockers in which to store your belongings.

During your appointment, you will be asked to lie very still on a comfortable bed with your head and upper body in the scanner (see images throughout this leaflet). Your head will be surrounded by a cage-like structure (see the image on page 8). You will hear a loud repetitive banging noise once the scan starts. Ear-plugs will be provided.

During the entire examination the radiographer can see you clearly and talk to you through a two-way intercom, so if you have any problems, you only have to speak. A member of the research team will also be in the scanner room with you. There is a button that you can press to stop the scan immediately at any time.

We would like to see what happens in your brain at a time of rest and when you experience pain. You will be asked to lie still throughout the scan. Initially, we will look at your brain at rest – all you have to do is try not to fall asleep! We will then assess your response to pain. This will be done by repeatedly using a mild pin-prick just above your bikini line. Again this may be painful briefly but will leave no lasting sensation of pain and no skin damage. This is done using a fine nylon fibre. Your scan will last up to 60 minutes. We will also take about a 15 ml blood sample (about a tablespoon full) to measure your hormone levels. We will ask your consent to use any leftover samples in other related research studies.

You will be asked to come in again for a further scan 3 months later before you finish on the study drug.

Reasonable travel expenses will be reimbursed for these visits.

Can I see the MRI system?

You are very welcome to visit CRIC (image 2) and see the MRI system.

What are the possible benefits of taking part?

There will be no direct benefit of taking part and you are free to withdraw at any time. However, we hope the information gained from these additional scans will help us understand how the drug gabapentin helps relieve pain.

What happens if something unexpected is found on the scan?

In the unlikely event that we see any abnormalities on your scan, a clinical specialist will discuss the implications with you and arrange for further investigations as necessary. Your GP will also be informed. However it is important to note that we do not carry out scans for diagnostic purposes and therefore these scans are not suitable for clinical interpretation. Our scans are intended for research purposes only.

Will my taking part in this study be kept confidential?

Yes. All information collected about you during the course of the research will be kept strictly confidential. Your personal details will be removed from all data prior to analysis.

What will happen to the results of the research study?

The results of this study will be published e.g. in medical journals, reports and textbooks. The anonymised data will be stored for ten years at the University of Edinburgh and may be considered for possible use in future projects.

Who is organising the research?

The research is being organised by Prof Andrew Horne (Consultant Gynaecologist) from the University of Edinburgh. The study is co-sponsored by the University of Edinburgh and NHS Lothian. The study is supported by Birmingham Clinical Trials Unit.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak with the clinical researchers who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do so through the NHS Complaints Procedure. Contact: Freepost NHS Lothian, 2-4 Waterloo Place, Edinburgh, EH1 3EG. Phone 0131 536 3370. Email complaints.team@nhslothian.scot.nhs.uk.

Who has reviewed the study?

This study has been given a favourable ethical opinion for conduct in the NHS by National Research Ethics Committee – Coventry and Warwickshire.

Contact details:

You may contact our clinical research team directly by telephoning (Research Nurse) on 0131 242 1000 for further information at any time. If you require any further information from a doctor who is not involved in any way in this study you can contact Dr Colin Duncan, Consultant Gynaecologist, Royal Infirmary of Edinburgh on 0131 242 1000.

Thank you for reading this information sheet.

Image 1 – CRIC, Edinburgh

Image 2 - Scanner

Image 3 - fMRI