# The action of gabapentin for the management of chronic pelvic pain in women (GaPP)

Submission date 16/12/2011	<b>Recruitment status</b> No longer recruiting	<ul><li>Prospectively registered</li><li>Protocol</li></ul>		
Registration date 28/02/2012	Overall study status Completed	<ul><li>Statistical analysis plan</li><li>[X] Results</li></ul>		
<b>Last Edited</b> 02/07/2020	<b>Condition category</b> Musculoskeletal Diseases	☐ Individual participant data		

#### Plain English summary of protocol

Background and study aims

Chronic pelvic pain (CPP) affects more than 1 million women in the UK. Annual healthcare costs are estimated at more than £150 million. Proven treatments for CPP are limited and are often unsatisfactory. Gabapentin is increasingly prescribed due to reports of effectiveness in other chronic pain conditions but there is not enough data supporting its use in CPP specifically. This study aims to measure the effectiveness of gabapentin in the treatment of women with chronic pelvic pain with no known cause.

Who can participate?

Women aged between 18 and 50 who have experienced pelvic pain for more than 6 months.

What does the study involve?

Participants will be randomly allocated to receive either gabapentin or a dummy pill (placebo) daily for 6 months.

What are the possible benefits and risks of participating? Participants may experience a reduction in their pelvic pain.

Where is the study run from? Royal Infirmary of Edinburgh (UK)

When is the study starting and how long is it expected to run for? February 2012 to November 2013

Who is funding the study? Chief Scientist Office (CSO) (UK)

Who is the main contact?
Dr Andrew Horne
Royal Infirmary of Edinburgh (UK)

# Contact information

#### Type(s)

Scientific

#### Contact name

Dr Andrew Horne

#### Contact details

Medical Research Council Centre for Reproductive Health Queen's Medical Research Institute Royal Infirmary of Edinburgh 47 Little France Crescent Edinburgh United Kingdom EH16 4SA

# Additional identifiers

#### Protocol serial number

Version 1

# Study information

#### Scientific Title

A pilot randomised controlled trial of the efficacy and mechanism of action of Gabapentin for the management of chronic Pelvic Pain in women (GaPP)

#### Acronym

GaPP

#### **Study objectives**

The aim of this study is to assess recruitment and retention rates and to obtain data to refine the research methodology for a full randomised controlled trial investigating the efficacy and mechanism of action of gabapentin for the management of chronic pelvic pain in women.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Scotland A Research Ethics Committee, 26/01/2011, ref: 12/SS/0005

# Study design

Two-arm parallel group pilot trial

# Primary study design

Interventional

# Study type(s)

**Treatment** 

## Health condition(s) or problem(s) studied

Chronic pelvic pain

#### **Interventions**

Gabapentin versus placebo.

300mg dose increasing in weekly increments to a maximum dose of 2700 mg if pain has not been reduced by 50% each week.

Daily administration (TID) and by oral capsule, treatment given for 6 months.

#### Intervention Type

Drug

#### Phase

Not Applicable

# Drug/device/biological/vaccine name(s)

Gabapentin

#### Primary outcome(s)

Determine whether it is possible to achieve acceptable recruitment and retention rates in two centres (NHS Lothian and NHS Grampian)

## Key secondary outcome(s))

- 1. To determine the effectiveness and acceptability to patients of the proposed methods of recruitment, randomisation, drug treatments, use of brain functional magnetic resonance imaging (fMRI) and follow-up
- 2. To determine whether fMRI of the brain is a sensitive approach to determine the mechanism of action of gabapentin in the management of CPP
- 3. To determine whether gabapentin is likely to be cost effective given the current level of evidence and uncertainty, and to ascertain what further evidence is needed for the evaluation of gabapentin

## Completion date

01/11/2013

# **Eligibility**

#### Key inclusion criteria

- 1. Women aged between 18-50
- 2. Consented to a routine diagnostic laparoscopy
- 3. Pelvic pain of > 6 months
- 4. Pain located within the true pelvis or between and below anterior iliac crests, associated functional disability
- 5. No obvious pelvic pathology

# Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Adult

## Lower age limit

18 years

# Upper age limit

50 years

#### Sex

Female

#### Key exclusion criteria

- 1. Known pelvic pathology e.g. endometriosis, cyst
- 2. Undergoing major surgery eg hysterectomy
- 3. Estimated Glomerular Filtration Rate (eGFR) >60

#### Date of first enrolment

01/02/2012

#### Date of final enrolment

01/11/2013

# Locations

#### Countries of recruitment

**United Kingdom** 

Scotland

## Study participating centre Royal Infirmary of Edinburgh

Edinburgh United Kingdom EH16 4SA

# Sponsor information

#### Organisation

University of Edinburgh (UK)

#### **ROR**

# Funder(s)

# Funder type

Government

#### Funder Name

Chief Scientist Office (CSO) (UK)

# Alternative Name(s)

CSO

# **Funding Body Type**

Government organisation

# **Funding Body Subtype**

Local government

#### Location

**United Kingdom** 

# **Results and Publications**

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration

# Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	12/04/2016		Yes	No
Results article	results	27/06/2019	02/07/2020	Yes	No
<u>Protocol article</u>	protocol	08/06/2012		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes