

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

Submission date 16/12/2011	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 28/02/2012	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 02/07/2020	Condition category 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.

Type(s)

Scientific

Contact name

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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

Primary study design

Interventional</

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

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

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
Protocol article </					