# The effectiveness of gabapentin in the treatment of chronic pelvic pain in women

Submission date 25/11/2015	<b>Recruitment status</b> No longer recruiting	[X] Prospectively registered [X] Protocol
<b>Registration date</b> 25/11/2015	<b>Overall study status</b> Completed	<ul> <li>[] Statistical analysis plan</li> <li>[X] Results</li> </ul>
Last Edited 30/12/2022	<b>Condition category</b> Signs and Symptoms	[] Individual participant data

### Plain English summary of protocol

Background and study aims

Chronic pelvic pain (CPP) in women is where pain is felt in the pelvic region (the area below the belly button and between the hips) for at least 6 months. It affects more than 1 million women in the UK every year, accounting for about 20% of all gynaecologist appointments. Despite this, there are a limited amount of effective treatments available, especially when the cause of the pain cannot be identified. In recent years, a drug called gabapentin is being prescribed more and more to treat people with CPP. It was belongs to a group of medications used to treat epilepsy, but it is also now used to treat a range of long-term pain conditions. Although gabapentin is being increasingly prescribed to people with CPP, there is not enough evidence to say whether it is an effective treatment. The aim of this study is to find out whether treatment with gabapentin an effective way of treating CPP in women.

Who can participate?

Women who are suffering from CPP with on obvious cause.

### What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group are given 300mg gabapentin to take orally (by mouth). Participants start by taking one 300mg capsule a day, and increase this dose by one 300mg capsule every three days (up to a maximum dose of nine 300mg capsules a day) until they are getting enough pain relief or start to experience side-effects. Those in the second group are given identical-looking placebo (dummy) capsules to take in the same way. At the start of the study and then after 16 weeks, participants complete a number of questionnaires in order to measure their pain levels and how well they have been coping with daily life physically and emotionally.

What are the possible benefits and risks of participating? Not provided at time of registration.

Where is the study run from? Birmingham Clinical Trials Unit (UK) When is the study starting and how long is it expected to run for? November 2015 to August 2017

Who is funding the study? National Institute for Health Research (UK)

Who is the main contact? Miss Afia Sajid

# **Contact information**

**Type(s)** Public

**Contact name** Miss Afia Sajid

### Contact details

Birmingham Clinical Trials Unit School of Health & Population Sciences College of Medical and Dental Sciences Public Health Building University of Birmingham Birmingham United Kingdom B15 2TT

# Additional identifiers

**EudraCT/CTIS number** 2014-005035-13

**IRAS number** 

ClinicalTrials.gov number

Secondary identifying numbers 19702

# Study information

### Scientific Title

GaPP 2: A multicentre randomised controlled trial of the efficacy and mechanism of action of gabapentin for the management of chronic pelvic pain in women

### Study objectives

The aim of this study is to find out whether gabapentin is a safe and effective treatment for chronic pelvic pain (CPP) in women.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

West Midlands - Coventry & Warwickshire Research Ethics Committee, 03/02/2015, ref: 15/WM /0036

**Study design** Double-blind multi-centre randomised controlled trial

**Primary study design** Interventional

**Secondary study design** Randomised controlled trial

**Study setting(s)** Other

**Study type(s)** Treatment

### Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

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

Topic: Reproductive health and childbirth; Subtopic: Reproductive Health and Childb (all Subtopics); Disease: General Gynaecology

### Interventions

Participants will be randomised in an equal (1:1) ratio to take either gabapentin or placebo.

Group 1: Participants are given gabapentin to take orally for the study period. Participants will start on 1 capsule (300 mg) daily and will increase by 1 capsule (300 mg) increments every three days until they perceive that they are gaining adequate pain relief, or report side effects (e.g. dizziness, somnolence, mood changes, appetite and poor concentration), precludes them from further increases, up to a maximum dose of 9 capsules (2700 mg). The titration phase will last a maximum of 4 weeks. If necessary they will be titrated down to the last tolerated dose with minimal side effects and asked to maintain this dose for the next 12 weeks.

Group 2: Participants are given placebo capsules to take orally for the study period.

Participants complete questionnaires at baseline and 16 weeks to assess pain levels and physical /emotional functioning.

Intervention Type

**Phase** Not Applicable

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

Gabapentin

### Primary outcome measure

Pelvic pain is measured using a numerical rating scale (NRS) at baseline and 13-16 weeks post-randomisation

### Secondary outcome measures

Physical/emotional functioning is assessed using questionnaires at baseline and week 16

**Overall study start date** 11/11/2015

### **Completion date**

01/02/2019

# Eligibility

### Key inclusion criteria

1. Women aged between 18-50 years

2. Chronic pelvic pain (non-cyclical with or without dysmenorrhoea or dyspareunia) of >3 months duration

3. Pain located within the true pelvis or between and below anterior iliac crests

4. No obvious pelvic pathology at laparoscopy (laparoscopy must have taken place at least 2 weeks ago, but no more than 36 months prior to screening)

5. Using or willing to use effective contraception if necessary to avoid pregnancy

6. Able to give informed consent

7. For both the worst and average pre-randomisation Numerical Rating Scale (NRS) questions, at least three of the four weekly scores returned to the trials office. At least two of the worst pain scores should be ≥4

Participant type(s)

Patient

**Age group** Adult

Lower age limit

**Upper age limit** 50 Years

**Sex** Female

### Target number of participants

Planned Sample Size: 300; UK Sample Size: 300

Total final enrolment

### Key exclusion criteria

1. Known pelvic pathology: o Endometriosis (macroscopic lesions) o complex or >5cm ovarian cyst o fibroid >3cm o dense adhesions

- 2. Current malignancy under treatment
- 3. Current use of gabapentin/pregabalin
- 4. Taking GnRH agonists and unable/unwilling to stop
- 5. Surgery planned in the next 6 months
- 6. History of significant renal impairment
- 7. Previous reaction to gabapentin
- 8. Breast feeding
- 9. Pregnancy
- 10. Planned pregnancy in next 6 months
- 11. Pain suspected to be of gastrointestinal origin (positive Rome III Diagnostic Criteria)
- 12. Prohibited medications (see SmPC Appendix 2))
- 13. Metal implant/pacemaker/claustrophobia (fMRI subgroup only)
- 14. Co-enrolment in another CTIMP

### Date of first enrolment

30/11/2015

Date of final enrolment 31/01/2019

## Locations

**Countries of recruitment** England

United Kingdom

Study participating centre Birmingham Clinical Trials Unit School of Health & Population Sciences College of Medical and Dental Sciences Public Health Building University of Birmingham Birmingham United Kingdom B15 2TT

# Sponsor information

### Sponsor details

The Queen's Medical Research Institute Royal Infirmary of Edinburgh 51 Little France Crescent Old Dalkeith Road Edinburgh Scotland United Kingdom EH16 4SA

### Sponsor type

University/education

#### ROR

https://ror.org/01nrxwf90

# Funder(s)

**Funder type** Government

**Funder Name** National Institute for Health Research

#### Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

**Funding Body Type** Government organisation

Funding Body Subtype National government

**Location** United Kingdom

# **Results and Publications**

**Publication and dissemination plan** Not provided at time of registration

Intention to publish date

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	31/01/2018		Yes	No
Results article	results	26/09/2020	30/09/2020	Yes	No
Results article		01/11/2020	30/12/2022	Yes	No
HRA research summary			28/06/2023	No	No