

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

Submission date 25/11/2015	Recruitment status No longer recruiting	☒ Prospectively registered ☒ Protocol
Registration date 25/11/2015	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 30/12/2022	Condition category 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 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 is an effective way of treating CPP in women.

Who can participate?

Women who are suffering from CPP with no 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

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Additional identifiers

Clinical Trials Information System (CTIS)

2014-005035-13

Protocol serial number

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)

Primary study design

Interventional

Study design

Double-blind multi-centre randomised controlled trial

Study type(s)

Treatment

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

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Gabapentin

Primary outcome(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Upper age limit

50 Years

Sex

Female

Total final enrolment

306

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

United Kingdom

England

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

Organisation

University of Edinburgh

ROR

<https://ror.org/01nrxf90>

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

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?
Results article	results protocol	26/09/2020	30/09/2020	Yes	No
Results article		01/11/2020	30/12/2022	Yes	No
Protocol article		31/01/2018		Yes	No
HRA research summary			28/06/2023	No	No