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

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

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

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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
Drug

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
18 Years

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
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Sponsor information

Organisation
University of Edinburgh

Sponsor details
The Queen’s Medical Research Institute
Royal Infirmary of Edinburgh
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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