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

Submission date
16/12/2011

Recruitment status
No longer recruiting

Registration date
28/02/2012

Overall study status
Completed

Last Edited
02/07/2020

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
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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

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

https://ror.org/01nrxwf90

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	protocol	08/06/2012		Yes	No
HRA research summary			28/06/2023	No	No