Clinical trial results:
GaPP1: A pilot randomised controlled trial of the efficacy and mechanism of action of gabapentin for the management of chronic pelvic pain in women

Summary

EudraCT number	2011-005494-22
Trial protocol	GB
Global end of trial date	19 March 2014

Results information

Result version number	v1 (current)
This version publication date	12 June 2019
First version publication date	12 June 2019

Trial information

Trial identification

Sponsor protocol code	01

Additional study identifiers

ISRCTN number	ISRCTN70960777
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-
Other trial identifiers	REC: 12/SS/0005

Notes:

Sponsors

Sponsor organisation name	University of Edinburgh
Sponsor organisation address	QMRI, 51 Little France Crescent, Edinburgh, United Kingdom, EH16 4TJ
Public contact	Ann Doust, University of Edinburgh, 0044 01312429492, ann.doust@ed.ac.uk
Scientific contact	Ann Doust, University of Edinburgh, 0044 01312429492, ann.doust@ed.ac.uk
Sponsor organisation name	NHS Lothian
Sponsor organisation address	QMRI, 51 Little France Crescent, Edinburgh, United Kingdom, EH16 4TJ
Public contact	Ann Doust, University of Edinburgh, 0044 01312429492, ann.doust@ed.ac.uk
Scientific contact	Ann Doust, University of Edinburgh, 0044 01312429492, ann.doust@ed.ac.uk

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No	No

1901/2006 apply to this trial?	

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	23 July 2014
Is this the analysis of the primary completion data?	Yes
Primary completion date	19 March 2014
Global end of trial reached?	Yes
Global end of trial date	19 March 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective is to determine whether it is possible to achieve acceptable recruitment and retention rates in two UK centres (NHS Lothian and NHS Grampian) within defined inclusion/exclusion criteria.

Protection of trial subjects:

A Data Monitoring Committee was appointed and met twice throughout the trial.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	10 September 2012
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United Kingdom: 47
Worldwide total number of subjects	47
EEA total number of subjects	47

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	47
From 65 to 84 years	0

85 years and over	0

Subject disposition

Recruitment

Recruitment details:

We recruited 47 women (30 from Edinburgh, 17 from Aberdeen) over a period from 10/09/2012 to 19/09/2013. Participants were recruited from gynaecology outpatient departments in both centres.

Pre-assignment

Screening details:

Participants were referred to the research team by their clinical team

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst

Arms

Are arms mutually exclusive?	Yes
Arm title	Active arm

Arm description: -

Arm type	Active comparator
Investigational medicinal product name	Gabapentin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Starting daily dose of 300 mgs increasing in increments of 300mgs weekly to a maximum daily dose of 2700 mgs. This was taken orally in capsule form.

Arm title	Placebo arm

Arm description: -

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

1 capsule a day rising to a maximum of 9 capsules per day over 9 weeks

Number of subjects in period 1	Active arm	Placebo arm
Started	22	25
Completed	11	12
Not completed	11	13
Consent withdrawn by subject	3	-
Physician decision	-	1

Adverse event, non-fatal	3	3
Wanted to try for pregnancy	2	-
Lost to follow-up	1	8
Lack of efficacy	2	1

Baseline characteristics

Reporting groups	
Reporting group title	Active arm
Reporting group description: -	
Reporting group title	Placebo arm
Reporting group description: -	

Reporting group values	Active arm	Placebo arm	Total
Number of subjects	22	25	47
Age categorical			
Study inclusion criterion stipulated an age range of 18-50 years			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	22	25	47
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous			
Units: years			
median	26	27	
full range (min-max)	18 to 43	18 to 42	-
Gender categorical			
All subjects were female			
Units: Subjects			
Female	22	25	47
Male	0	0	0

End points

End points reporting groups

Reporting group title	Active arm
Reporting group description: -	
Reporting group title	Placebo arm
Reporting group description: -	
Subject analysis set title	Recruitment and retention rates (active)
Subject analysis set type	Full analysis

Subject analysis set description:

Using the information collected from the participant log, we will determine the number of patients recruited from the pool of eligible women and a >50% recruitment will be deemed acceptable. While a retention rate of 100% would be ideal, we will consider a rate of 90% satisfactory. We will provide an estimate of the proportion and its 95% confidence interval. In addition, we will determine the nature and number of unanswered questions in each questionnaire and identify reasons for non-response through the focus groups and participant interviews in order to optimise data collection in the future trial.

Subject analysis set title	recruitment and retention (placebo)
Subject analysis set type	Full analysis

Subject analysis set description:

recruitment and retention rates (placebo)

Primary: Proportion of eligible patients randomised into the study

End point title	Proportion of eligible patients randomised into the study

End point description:

End point type	Primary

End point timeframe:

12 months

End point values	Recruitment and retention rates (active)	recruitment and retention (placebo)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	47	47		
Units: Number of patients randomised	22	25		

Statistical analyses

Statistical analysis title	Recruitment and retention rates
Comparison groups	Recruitment and retention rates (active) v recruitment and retention (placebo)

Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other[1]
Parameter estimate	Proportion
Point estimate	34
Confidence interval	
level	95 %
sides	2-sided
lower limit	27
upper limit	43

Notes:

[1] - Estimate of a single proportion

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
From time of consent to last visit	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	22.0

Reporting groups	
Reporting group title	Active arm
Reporting group description: -	
Reporting group title	Placebo arm
Reporting group description: -	

Serious adverse events	Active arm	Placebo arm	
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 22 (9.09%)	0 / 25 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Gastrointestinal disorders			
All Gastrointestinal disorders			
subjects affected / exposed	2 / 22 (9.09%)	0 / 25 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 0.05 %

Non-serious adverse events	Active arm	Placebo arm	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	15 / 22 (68.18%)	16 / 25 (64.00%)	
Nervous system disorders			
All nervouse system disorders			
subjects affected / exposed	10 / 22 (45.45%)	7 / 25 (28.00%)	
occurrences (all)	26	22	
General disorders and administration site conditions			
All general disorders and administration site conditions			

subjects affected / exposed occurrences (all)	11 / 22 (50.00%) 17	6 / 25 (24.00%) 8	
Ear and labyrinth disorders Ear pain subjects affected / exposed occurrences (all)	 1 / 22 (4.55%) 23	 0 / 25 (0.00%) 0	
Eye disorders Vision blurred subjects affected / exposed occurrences (all)	 0 / 22 (0.00%) 0	 1 / 25 (4.00%) 1	
Gastrointestinal disorders All Gastrointestinal disorders subjects affected / exposed occurrences (all)	 6 / 22 (27.27%) 6	 8 / 25 (32.00%) 17	
Respiratory, thoracic and mediastinal disorders Epistaxis subjects affected / exposed occurrences (all)	 0 / 22 (0.00%) 0	 1 / 25 (4.00%) 1	
Skin and subcutaneous tissue disorders Pruritis subjects affected / exposed occurrences (all)	 0 / 22 (0.00%) 0	 1 / 25 (4.00%) 1	
Psychiatric disorders All psychiatric disorders subjects affected / exposed occurrences (all)	 3 / 22 (13.64%) 3	 3 / 25 (12.00%) 9	
Renal and urinary disorders All renal and urinary disorders subjects affected / exposed occurrences (all)	 0 / 22 (0.00%) 0	 2 / 25 (8.00%) 3	
Musculoskeletal and connective tissue disorders Backpain subjects affected / exposed occurrences (all) All musculoskeletal and connective tissue disorders	 1 / 22 (4.55%) 2	 0 / 25 (0.00%) 0	

subjects affected / exposed occurrences (all)	1 / 22 (4.55%) 2	1 / 25 (4.00%) 1	
Infections and infestations All infections and infestations subjects affected / exposed occurrences (all)	 2 / 22 (9.09%) 2	 5 / 25 (20.00%) 8	
Metabolism and nutrition disorders All metabolism and nutrition disorders subjects affected / exposed occurrences (all)	 2 / 22 (9.09%) 2	 1 / 25 (4.00%) 1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

http://www.ncbi.nlm.nih.gov/pubmed/22685224

http://www.ncbi.nlm.nih.gov/pubmed/27070434