Clinical trial results:
A 12 week, multi centre, open label study to evaluate the effect of fesoterodine flexible dosing regimen on the sexual function of women with overactive bladder.

Summary

EudraCT number	2010-023851-27
Trial protocol	GB
Global end of trial date	17 February 2017

Results information

Result version number	v1 (current)
This version publication date	13 October 2018
First version publication date	13 October 2018
Summary attachment (see zip file)	FINAL STUDY REPORT (FINAL STUDY REPORT.pdf)

Trial information

Trial identification

Sponsor protocol code	AMRPhD1

Additional study identifiers

ISRCTN number	ISRCTN40720691
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	King's College Hospital NHS Foundation Trust
Sponsor organisation address	Denmark Hill, London, United Kingdom, SE5 9RS
Public contact	Angela Rantell, King’s College Hospital NHS Foundation Trust, 0044 0203299 3568, angela.rantell@nhs.net
Scientific contact	Angela Rantell, King’s College Hospital NHS Foundation Trust, 0044 0203299 3568, angela.rantell@nhs.net

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 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	12 February 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	12 June 2016
Global end of trial reached?	Yes
Global end of trial date	17 February 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective is to assess the impact on sexual function, after 12 weeks flexible dose fesoterodine in women with OAB compared to baseline.

Protection of trial subjects:

At the screening visit the following were performed
- Weight, medical history (including any medication and non-drug treatment) and demographn.
- Sitting blood pressure and pulse.
- Physical examination.
- Urine dipstick test w to exclude blood and infection and Urine pregnancy test for women of child bearing potential.

Background therapy:

none

Evidence for comparator:

No comparator.

Actual start date of recruitment	01 May 2012
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United Kingdom: 30
Worldwide total number of subjects	30
EEA total number of subjects	30

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)	28
From 65 to 84 years	2
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants were recruited from four clinical sites within the United Kingdom between 12/10/2012 and 10/06/2016.

Pre-assignment

Screening details:

1. Female outpatients aged 18 – 80 years.
2. Overactive bladder symptoms (subject reported) for ≥3 months prior to screening visit according to ICS guidelines.
3. Mean number of Urgency episodes ≥3 per 24 hours as verified by the screening bladder diary prior to baseline / Visit 2.
4. Sexually active Able and willing to complete the micturition

Period 1

Period 1 title	Overall Trial (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Arm title	Full study

Arm description:

This was a multi-centre open label study which aimed to enter 132 female subjects with OAB symptoms. Sexual function and efficacy assessments was evaluated via 3-day bladder diaries, questionnaires (KHQ, PISQ-12, SQoL, PAC-QoL, SAGA, PPBC) and urodynamics. Tolerability and safety was evaluated at every visit with recording of adverse events.

Arm type	Experimental
Investigational medicinal product name	Fesoteradine
Investigational medicinal product code	
Other name	TOVIAZ
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

4mg daily for 28 days then option to either continue on same dose or dose escalate to 8mg for the next 56 days

Number of subjects in period 1	Full study
Started	30
Completed	20
Not completed	10
Consent withdrawn by subject	4
Physician decision	1
Pregnancy	1
Failed screening	2
Lost to follow-up	2

Baseline characteristics

Reporting groups

Reporting group title	Overall Trial

Reporting group description: -

Reporting group values	Overall Trial	Total	
Number of subjects	30	30	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	28	28	
From 65-84 years	2	2	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	30	30	
Male	0	0	

End points

End points reporting groups

Reporting group title	Full study

Reporting group description:

This was a multi-centre open label study which aimed to enter 132 female subjects with OAB symptoms. Sexual function and efficacy assessments was evaluated via 3-day bladder diaries, questionnaires (KHQ, PISQ-12, SQoL, PAC-QoL, SAGA, PPBC) and urodynamics. Tolerability and safety was evaluated at every visit with recording of adverse events.

Primary: PISQ-12

End point title	PISQ-12[1]

End point description:

Change in item scores of the Pelvic Organ Prolapse. Prolapse and Incontinence Sexual Quality of Life Questionnaire (PISQ-12), PISQ-12 is a self administered questionnaire consisting of 12 items.

End point type	Primary

End point timeframe:

From initial IMP dosing until 12 weeks post dose.

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Please see attached document for full results

End point values	Full study			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: questionnaire score				
number (not applicable)	20			

Attachments (see zip file)	RESULTS/FESOTERADINE OAB.pdf

Statistical analyses

No statistical analyses for this end point

Primary: Paired T-Test SQOL-F Total Score

End point title	Paired T-Test SQOL-F Total Score[2]

End point description:

End point type	Primary

End point timeframe:

From commencement of IMP to 12 weeks post.

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Please see attached document for full results

End point values	Full study			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: Questionnaire score				
number (not applicable)	20			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: Until Week 24 post commencement of dosing.	
Assessment type	Systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	17.1
Reporting groups	
Reporting group title	Whole Trial
Reporting group description: All participants	

Serious adverse events	Whole Trial		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 28 (3.57%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Pregnancy, puerperium and perinatal conditions			
Pregnancy			
subjects affected / exposed	1 / 28 (3.57%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Whole Trial		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	17 / 28 (60.71%)		
General disorders and administration site conditions			
Dry mouth			
subjects affected / exposed	10 / 28 (35.71%)		
occurrences (all)	10		
Ear and labyrinth disorders			
Labrynthitis			

subjects affected / exposed occurrences (all)	1 / 28 (3.57%) 1		
Eye disorders Blurred Vision subjects affected / exposed occurrences (all)	 1 / 28 (3.57%) 1		
Gastrointestinal disorders Bloating subjects affected / exposed occurrences (all) Constipation subjects affected / exposed occurrences (all)	 1 / 28 (3.57%) 1 1 / 28 (3.57%) 1		
Respiratory, thoracic and mediastinal disorders chest infection subjects affected / exposed occurrences (all)	 1 / 28 (3.57%) 1		
Infections and infestations Urinary tract infection subjects affected / exposed occurrences (all)	 2 / 28 (7.14%) 2		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
16 September 2013	Amendment to change IMP supply from clinical trial supplies to commercial stock.

Notes:

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/24369895