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The effect of fesoterodine flexible dosing regimen on the sexual function of women with overactive bladder

Submission date
20/01/2011

Recruitment status
No longer recruiting

Registration date
08/02/2011

Overall study status
Completed

Last Edited
21/06/2019

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Many women have lower urinary tract symptoms which include having to pass urine frequently or a desire to pass urine which is difficult to control, incontinence (the accidental loss of urine). These symptoms are most likely due to an overactive bladder (OAB). This study will involve the drug fesoterodine fumarate (from now on referred to as fesoterodine), which is a drug already licensed and routinely used in the UK for this condition. The study aims to assess whether this drug improves sexual function in women with overactive bladder. In addition it also aims to demonstrate if the drug reduces the amount of times patients need to pass urine. It will also assess how well tolerated fesoterodine is and look at how many women feel they need to change the dose of the medication to best manage their symptoms.

Who can participate?
Women aged 18 - 80 with overactive bladder symptoms

What does the study involve?
All participants are treated with fesoterodine taken orally once a day for four weeks. At this point the participant has a discussion with the study doctor and either stays on the same dose of medication for a further 8 weeks or they may decide to increase the dose for the remaining 8 weeks of the study. Once a decision has been made at that study visit the dosage cannot be changed for the remainder of the study. Participants may also have further bladder function tests performed at the end of the study if they are one of the first 40 patients who enter the study.

What are the possible benefits and risks of participating?
The medicine you receive may help relieve your symptoms of your overactive bladder, but this cannot be guaranteed and you may not receive any direct benefit from taking part in this study. The information we gain from this study might help us to treat future patients with overactive bladder. There is a possibility that fesoterodine might not work for you or might not work as well as another medicine. There could be risks to an unborn child in this study. If you are pregnant or may become pregnant during the study, these risks could affect you or your unborn

child. Unless you have been surgically sterilised (you have had your womb and/or ovaries removed) or are postmenopausal you must agree to use birth control during the study. Your study doctor must approve the form of birth control.

Where is the study run from?
King's College Hospital (UK)

When is the study starting and how long is it expected to run for?
February 2011 to June 2017

Who is funding the study?
Pfizer (UK)

Who is the main contact?
Angela Rantell

Contact information

Type(s)
Scientific

Contact name
Miss Angela Rantell

Contact details
King's College Hospital
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London
United Kingdom
SE5 9RS

Additional identifiers

Clinical Trials Information System (CTIS)
2010-023851-27

Protocol serial number
EudraCT: 2010-023851-27

Study information

Scientific Title
A 12 week, single centre, open label study to evaluate the effect of fesoterodine flexible dosing regimen on the sexual function of women with overactive bladder

Study objectives
Null hypothesis:
Fesoterodine has no effect on sexual function in women complaining of overactive bladder syndrome.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Single-centre open-label prospective observational study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Overactive bladder syndrome

Interventions
All patients have a two week wash out period and are then started on Fesoterodine fumarate 4mg taken orally once a day for four weeks. At this point the patient will have a discussion with the study doctor and will either stay on the same dose of medication for a further 8 weeks or they may decide to up titrate to fesoterodine fumarate 8mg taken orally once a day for the remaining 8 weeks of the trial. Once a decision has been made at that study visit the dosage cannot be changed for the remainder of the trial.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Fesoterodine

Primary outcome(s)
Change in item scores of the Pelvic Organ Prolapse and Urinary Incontinence Sexual Questionnaire - short form (PISQ-12) and the Sexual Quality of Life questionnaire (SQOL) at week 12 relative to baseline

Key secondary outcome(s))
1. Bladder diary:
1.1. Change in mean number of micturitions per 24hours at week 12 relative to baseline
1.2. Change in mean number of nocturnal micturitions per 24 hours at week 12 relative to baseline in subjects with greater than 0 episodes during the 3-day baseline diary period. (Nocturnal micturitions are defined as those occurring between the time the subject goes to bed with the intention of sleeping and the time she rises to start the next day).
1.3. Percentage change in urinary urgency incontinence (UUI) episodes per 24 hours at week 12 relative to baseline in subjects with greater than 0 UUI episodes during the 3-day baseline diary period
1.4. Change in mean number of urgency episodes per 24 hours at week 12 relative to baseline.

(Urgency episodes are defined as those with a Patient Perception of Intensity of Urgency Score (PPIUS) rating of greater than or equal to 3 in the diary.
1.5. Percentage change in urgency episodes per 24 hours at week 12 relative to baseline
2. Patient questionnaires:
2.1. Patient Perception of Bladder Condition (PPBC): change in PPBC at week 12 relative to baseline
2.2. King's Health Questionnaire (KHQ): change in total score of each domain at week 12 relative to baseline
2.3. Patient Assessment of Constipation Quality of Life Questionnaire (PAC-QOL): change in total score of each domain at week 12 relative to baseline
2.4. Self Assessment Goal Achievement Questionnaire (SAGA): achievement of patient orientated goals at 12 weeks relative to baseline

Completion date
30/06/2017

Eligibility

Key inclusion criteria
Subjects must meet all of the following inclusion criteria to be eligible for enrolment into the trial:
1. Female outpatients aged 18 - 80 years
2. Overactive bladder symptoms (subject reported) for greater than or equal to 3 months prior to screening visit according to International Continence Society (ICS) guidelines
3. Mean urinary frequency of greater than or equal to 8 micturitions per 24 hours as verified by the screening bladder diary prior to baseline/visit 2
4. Mean number of urgency episodes greater than or equal to 3 per 24 hours as verified by the screening bladder diary prior to baseline/visit 2
5. Sexually active with a mean frequency of sexual activity greater than or equal to 1 per week
6. Able and willing to complete the micturition bladder diaries and all trial related questionnaires, comply with scheduled clinic visits and clinical trial procedures
7. Capability of understanding and having signed the informed consent form after full discussion of the treatment and its risks and benefits

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Total final enrolment

Key exclusion criteria

Subjects presenting with any of the following will not be included in the trial:
1. Any condition that would contraindicate the use of fesoterodine including, but not limited to:
1.1. Hyposensitivity to the active substance (fesoterodine fumarate) or any of the excipients, or to peanut or soya
1.2. Urinary retention
1.3. Gastric retention
1.4. Uncontrolled narrow angle glaucoma
1.5. Myasthesia gravis
1.6. Moderate or severe hepatic impairment
1.7. Severe renal impairment
1.8. Severe ulcerative colitis
1.9. Toxic megacolon
2. Stage 3 or greater pelvic organ prolapse, defined as tissue protuding to or beyond the introitus in lithotomy position at rest (without increase in intra abdominal pressure)
3. History of lower urinary tract surgery (e.g. incontinence surgery, diverticulectomy, OTIS urethrotomy) with the exception of any minor surgery (e.g. Cystoscopic procedures)
4. A known history of interstitial cystitis or a significant pain component associated with OAB symptoms, uninvestigated haematuria, urogenital cancer, interstitial or external radiation to the pelvis or external genitalia, or bladder outlet obstruction, radiation cystitis, genitor-urinary tuberculosis, bladder calculi, urethral obstruction or detrusor-sphincter dysynergia
5. Subjects with bladder stones. Subjects with a previous history of bladder stones may be included.
6. Previous history of acute urinary retention requiring catheterisation, clinically relevant bladder outlet obstruction or severe voiding difficulties in the judgement of the investigator prior to visit 2 (baseline)
7. Use of an indwelling or an intermittent self-catheterisation programme
8. Symptoms of incontinence being predominantly stress urinary incontinence as determined by the investigator
9. Urinary tract infection (UTI) as shown by the results of the urinalysis at screening or recurrent urinary tract infections (RUTIs) defined as treatment for UTI greater than or equal to 3 times in the last year
10. Use of any electrostimulation, bladder training, or pelvic floor exercises (with certified incontinence practitioners) within 4 weeks prior to Visit 1 (screening)
11. Treatment with antimuscarinic OAB medication with 2 weeks prior to visit 2 (baseline), including any preparation containing: darifenacin, oxybutynin, propiverine, tolterodine, fesoterodine, solifenacin and trospium
12. Initiation of treatment during the 12 week trial period with:
12.1. Any other drug treatment for OAB
12.2. Any drugs with significant anticholinergic, antispasmodic, parasympathetic, or cholinergic agonistic effects
13. Intermittent or unstable use of diuretics or alpha blockers, or tricyclic antidepressants, oestrogen therapy and any 5AR inhibitors or initiation of such treatment(s) within 2 weeks prior to visit 2 (baseline)
14. Treatment with moderate or potent CYP3A4 inhibitors, such as grapefruit juice, macrolide antibiotics (erythromycin, clarithromycin), immunosuppressants (cyclosporine), azole antifungal agents (ketonazole, itraconazole), protease inhibitors within 3 weeks prior to visit 2 (baseline), or the expectation to start such a treatment during the trial
15. Administration of medication capable of inducing hepatic enzyme metabolism or transport (e.

g. barbiturates, rifampicin, carbemazipine, phenytoin, primidone, or St John's Wort)
16. Participated in any clinical trial or received an investigational drug within 4 weeks prior to visit 2
17. History of alcohol abuse and/or any other drug in the opinion of the investigator
18. Female subjects who are pregnant, nursing, or who are intending to become pregnant during the trial or within three months after the completion of the trial
19. Female subjects of childbearing potential who are heterosexually active but not using an adequate form of contraception. Reliable contraception methods defined as hormonal methods of contraception (including oral, patches, injected, implants, IUDs, condom with spermicidal foam /gel/film/cream/suppository, tubal ligation male partner who has had a vasectomy for a least 4 months).
20. Subjects who have any medical (including known history of major haematological, renal, cardiovascular or hepatic abnormalities) or psychological condition or social circumstances that would impair their ability to participate reliably in the trial, or those who may increase the risk to themselves or others by participating
21. Has any current malignancy except
21.1. Those greater than or equal to 5 years ago without recurrence
21.2. Excised basal cell skin carcinoma or squamous cell cancer
22. Subjects who, in the opinion of the investigator, are not likely to complete the trial for any reason

Date of first enrolment
01/02/2011

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
King's College Hospital
United Kingdom
SE5 9RS

Study participating centre
St Mary's Hospital
United Kingdom
W2 1NY

Study participating centre

Croydon University Hospital
United Kingdom
CR7 7YE

Study participating centre
Medway Maritime Hospital
United Kingdom
ME7 5NY

Sponsor information

Organisation
King's College Hospital NHS Foundation Trust (UK)

ROR
https://ror.org/01n0k5m85

Funder(s)

Funder type
Industry

Funder Name
Pfizer UK

Alternative Name(s)
Pfizer Ltd, Pfizer Limited

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results			21/06/2019	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes