12-week, randomized, double-blind, double-dummy, placebo-controlled, parallel-group, multicenter trial to evaluate the efficacy and safety of fesoterodine in comparison to tolterodine ER in patients with overactive bladder.

Published: 24-07-2007
Last updated: 08-05-2024

To compare the efficacy of fesoterodine to placebo and tolterodine ER in subjects with overactive bladder after 12 weeks of treatment.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Bladder and bladder neck disorders (excl calculi)
Study type	Interventional

Summary

ID

NL-OMON31014

Source
ToetsingOnline

Brief title
A0221008

Condition

- Bladder and bladder neck disorders (excl calculi)

Synonym
loss of urinary, urgency urinary incontinence

Research involving
Human

Sponsors and support

Primary sponsor: Pfizer
Source(s) of monetary or material Support: Pfizer bv

Intervention

Keyword: Double-blind, Overactive Bladder, Placebo controlled, randomized

Outcome measures

Primary outcome

Change in mean number of urgency urinary incontinence (UUI) episodes per 24

hours at week 12 relative to the baseline (UUI episodes are defined as those

with Bladder Sensation Scale rating of 5 in the diary)

Secondary outcome

Patient's perception of Bladder Condition (PPBC)

Patient perception of Urgencu Scale (PPUS)

Overactive bladder questionnaire (OAB-q)

Dispense micturition bladder diary (3-day)

Evaluation of micturition bladder diary (3-day)

Study description

Background summary

Overactive bladder is a symptom complex of urgency, with or without urgency incontinence, usually with frequency. Overactive bladder affects at least 10% of the overall adult population. The majority of diagnosed patients are women, who either develop Overactive bladder in combination with some degree of stress incontinence or as pure OAB. As shown in the phase 3 studies, fesoterodine (antimuscarinic for OAB treatment) has two effective, safe, and well tolerated doses: 4mg and 8mg. Fesoterodine has been developed at a higher 8 mg dose that offers opportunity for dose flexibility and individualization.

Study objective

To compare the efficacy of fesoterodine to placebo and tolterodine ER in subjects with overactive bladder after 12 weeks of treatment.

Study design

This is a 12-week, randomized, double-blind, double-dummy, placebo-controlled, parallel-group, Phase 3b, multicenter trial with fesoterodine versus tolterodine and placebo in subjects with an overactive bladder. The subjects will be sinitially screened at screening/enrolment visit. The randomized subjects will be received the assigned treatment: fesoterodine, tolterodine and placebo treatment for 12 weeks. Approximately 1675 subjects will be randomized in this trial. The trail requirs total of 5 in-clinic visits. The trial takes 14 weeks incl. 2 weeks of follow-up.

Intervention

4 and 8 mg fesoterodine, 4 mg tolterodine and placebo, daily for 12 weeks.

Study burden and risks

Patients may undergo serveral treatments, such as physical examination, including measurement of the vital signs (blood pressure and heart rate), collection of blood samples and electrocardiogram (ECG). Patients will be given a diary (4 times), 10 questionnaires to complete and collect an urine sample during 12 weeks.

The common site effects of fesoterodine are: dry mouth, constipation, urinaru tract infection, indigestion, dry eyes, dry throat, dirricult of painful urination, abdominal pain, nasopharyngitis, back pain, headache, in ability to urinate, blurred or abnormal vision. Serious side effects, for example, chest pain and heart attack, were also reported in the fesoterodine studies.

The common site effects of tolterodine are: dry mouth, headache, fatique, dizziness, constipation, abdominal pain, indigestion, dry eyes, abnormal vision, sleepiness, anxiety, difficult or painful urination, in ability to urinate.

The blood draw requires a needle stick and it may hurt, the patient may get a bruise, an infection, feel dizzey or faint.

Contacts

Public
Pfizer

Rivium Westlaan 142
2909 LD Capelle a/d IJssel
Nederland
Scientific
Pfizer

Rivium Westlaan 142
2909 LD Capelle a/d IJssel
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Overactive bladder symptoms for more than 3 months prior to screening/enrolment visit (visit 1)
- Reported at least an everage of 1 UUI episode per 24 hours in the 3-day micturition diary prior to the randomization/baseline visit (visit 2)

Exclusion criteria

-Any condition that would contraindicate their usage of fesoterodine including: hypersensitivity to the active substance or to peanut or soya or any of the excipients, urinary retention, gastric retention, uncontrolled narrow angle glaucoma, myasthenia gravis, severe hepatic impairment, severe ulcerative colitis, and toxic megacolon.

-Clinically significant hepatic or renal disease, and/or with a screening test of AST,ALT, ALP, urea nitrogen, or creatinine greater than 1.5 times of the upper limit of normal range (ULN)
See for more exclusion criteria p.19-21

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	50
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Detrusitol ER
Generic name:	Tolterodine tartrate
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	niet bekend
Generic name:	Fesoterodine fumarate

Ethics review

Approved WMO

Date:	24-07-2007
Application type:	First submission
Approved WMO Date:	19-09-2007
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	09-01-2008
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
Other	Clinical trails.gov
EudraCT	EUCTR2006-006-935-3-NL
CCMO	NL17592.091.07