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A double-blind, placebo-controlled study to assess the safety and preliminary efficacy of PSD506 in treatment-naïve or previously treated (washed out) patients with symptoms of overactive bladder

Submission date	Recruitment status	[_] Prospectively registered
15/02/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/04/2007	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
22/05/2017	Urological and Genital Diseases	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PSD506-OAB-005

Study information

Scientific Title
A double-blind, placebo-controlled study to assess the safety and preliminary efficacy of PSD506 in treatment-naïve or previously treated (washed out) patients with symptoms of overactive bladder

Study objectives
Overactive bladder (OAB) is treated currently by anti-muscarinic drugs. Anti-muscarinic drugs may have cardiovascular side effects (such as tachycardia) and Central Nervous System (CNS) side effects. These side effects result from non-selective muscarinic blockade and from CNS penetration. PSD506 is a novel anti-muscarinic agent that is being developed for the treatment of OAB. This is the first study in patients suffering from OAB and will establish the efficacy of PSD506 in this condition as well as further assessing safety and tolerability in practice.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Central and South Bristol REC, 04/08/2006, ref: 06/Q2006/61

Study design
Multi-centre multi-national randomised double-blind placebo-controlled parallel-group study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

Interventions

Previously treated subjects will have a 4-week (28-day) washout period. All subjects will have a 1-week (7-day) run-in period.

PSD506 20 mg or matching placebo daily for 4 weeks (plus 4-week follow-up period).

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
PSD506 (antimuscarinic agent)

Primary outcome measure
Change from baseline in average number of micturitions per day (urinary frequency)

Secondary outcome measures
1. Change from baseline in average number of urge urinary incontinence episodes
2. Change from baseline in average number of urinary urgency episodes
3. Change from baseline in average volume voided per micturition
4. Change from baseline in scores on ICIQ-FLUTS SF or ICIQ-MLUTS SF
5. Change from baseline in score on ICIQ-OABqol

Overall study start date
01/07/2006

Completion date
31/12/2007

Eligibility

Key inclusion criteria
1. Age 18 years or over
2. If female, must be surgically sterile or post-menopausal for at least a year and confirmed by a negative hormone panel (luteinizing hormone [LH], follicle stimulating hormone [FSH], 17β estradiol). Women who are receiving HRT at the time of screening may be defined as post-menopausal provided there is documentation in their medical history to confirm that they had stopped menstruating for one year before starting the HRT
3. If male subject and partner is of childbearing potential must agree to use a secure form of contraception (e.g., pill, condom)
4. Involuntary detrusor contraction associated with urgency during filling cystometry in the last 12 months prior to study entry
5. Symptoms of OAB for at least 6 months prior to study entry. Subjects with concurrent Stress Urinary Incontinence (SUI) and OAB may be included provided the symptoms of OAB are dominant
6. Willing and able to provide written informed consent
Inclusion criteria at baseline:
7. Completed appropriate washout period (for previously treated subjects) and 7 days run-in period for all subjects (both treated subjects and treatment naïve subjects) prior to baseline visit

8. Have an average of 10 micturitions and at least one episode of urinary urgency per day (during the 7 days of run-in period)
9. Have an average of 7 episodes of urge urinary incontinence per week (during the 7 days of the run-in period)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100 subjects (50 subjects per group)

Key exclusion criteria
1. Female subject who is of childbearing potential
2. Uncontrolled hypertension, defined as mean systolic blood pressure [SBP] ≥160 mmHg or a diastolic blood pressure [DBP] ≥95 mmHg (after sitting for 5 minutes)
3. History of clinically significant hypotensive episodes or symptoms of fainting, dizziness or lightheadedness
4. Unstable cardiovascular disease, particularly coronary artery disease, arrhythmias, atrial tachycardia or congestive heart failure
5. Clinically significant central nervous system disease, including: Parkinsons disease, multiple sclerosis, transient ischemic attack, stroke, seizure disorder, depression or behavioral disturbances
6. History of peripheral vascular or cerebrovascular disease
7. History of narrow angle glaucoma or increased ocular pressure
8. Clinically significant bladder pathology (e.g., obstructive uropathy) or history of urinary retention
9. Clinically significant gastrointestinal disorder (e.g., gastroparesis, constipation, diarrhea, colitis, gastrointestinal tract obstruction, hiatal hernia with reflux oesophagitis, cholestasis)
10. History of clinically significant liver disease (e.g., hepatitis B)
11. Prohibited medications taken within the previous 2 weeks prior to baseline date (4 weeks for solifenacin)
12. Concomitant use of any agent that has a significant interaction with CYP3A4 or P glycoprotein (Pgp)
13. Clinically significant abnormalities in laboratory test results (including hepatic and renal panels, Complete Blood Count [CBC] and chemistry panel) at screening
14. Urinary tract infection within 6 weeks prior to baseline
15. Participation in an investigational drug or device study within 30 days prior to screening date
16. Known hypersensitivity to anti-cholinergic agents
17. Concomitant disease or condition that could interfere with, or for which the treatment might interfere with, the conduct of the study; or that would, in the opinion of the investigator, pose an unacceptable risk to the subject in this study. This would include, but is not limited to, cancer, alcoholism, drug dependency or abuse, or psychiatric disease

18. Unwillingness or inability to comply with the study protocol for any other reason
19. Unable to understand and complete the ICIQ-OABqol and ICIQ-FLUTS or ICIQ-MLUTS questionnaires or Micturition Diary
20. Any clinically significant abnormality on 12-lead ECG

Date of first enrolment
01/07/2006

Date of final enrolment
31/12/2007

Locations

Countries of recruitment
England

Germany

Ireland

United Kingdom

Study participating centre
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Funder type
Industry

Funder Name
Plethora Solutions Ltd (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration