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A double-blind, placebo-controlled, pilot study to assess the safety and preliminary efficacy of PSD506 in treatment-naïve or previously treated (washed out) patients with benign prostatic obstruction and lower urinary tract symptoms

Submission date
15/02/2007

Recruitment status
No longer recruiting

Registration date
20/04/2007

Overall study status
Completed

Last Edited
21/11/2019

Condition category
Urological and Genital Diseases

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

Clinical Trials Information System (CTIS)

2006-002055-3

Protocol serial number
PSD506-OAB-004

Study information

Scientific Title
A double-blind, placebo-controlled, pilot study to assess the safety and preliminary efficacy of PSD506 in treatment-naïve or previously treated (washed out) patients with benign prostatic obstruction and lower urinary tract symptoms

Study objectives
Symptoms of lower urinary tract dysfunction are associated with Bladder Outlet Obstruction (BOO) as a result of Benign Prostatic Enlargement (BPE). The symptoms experienced may be characteristic of OverActive Bladder (OAB) or secondary to Detrusor Overactivity (DO). OAB symptoms may be exacerbated by BOO that results from BPE. Treating the bothersome symptoms of OAB is therefore an important goal for the management of comorbid symptomatic DO and BOO. PSD506 is a novel antimuscarinic agent that is being studied for the treatment of OAB. This study aims to assess the safety of PSD506 in men with Lower Urinary Tract Symptoms (LUTS) and BPE/BOO and an International Prostatic Symptom Score (IPSS) of 8 -19, in line with American Urological Association recommendations.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Northern and Yorkshire Multi-centre REC, 13/07/2006, ref: 06/MRE03/32

Study design
Multicentre multinational randomised double-blind placebo-controlled parallel-group study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Men with LUTS and BPE/BOO

Interventions
PSD506 20 mg or matching placebo once daily for 4 weeks, with a two- to four-week run-in period, if required.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome(s)
To demonstrate the similarity in safety profiles between PSD506 and placebo as assessed by a urodynamic measure of bladder outlet obstruction (BOO).

Key secondary outcome(s))
1. To measure the change in Post Void Residual volumes (PVR) and other urodynamic parameters
2. To obtain a preliminary assessment of efficacy by measuring the change in International Prostatic Symptom Score (IPSS) from baseline
3. To demonstrate the overall safety of PSD506 in this subject population

Completion date
31/03/2007

Eligibility

Key inclusion criteria
1. Males aged 18 years and above
2. Symptoms of LUTS for ≥6 months prior to baseline
3. IPSS score of 8 - 19 at baseline
4. Maximum urine flow ≥5 ml/sec and ≤12 ml/sec on a minimum of 125 ml voided volume
5. Post-void residual volume <150 mL
6. Written informed consent
7. If male subject and partner are of childbearing potential, agree to use a secure form of contraception (e.g. oral or injectable contraceptive, condom)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Male

Key exclusion criteria
1. Uncontrolled hypertension >160/95 mmHg (after sitting for 5 minutes)
2. Concomitant or recent medication for BPE: 5α-reductase inhibitors within 6 months prior to baseline or alpha-adrenergic receptor blockers within 3 months prior to baseline
3. Use of anticholinergics in the two weeks prior to baseline (four weeks for solifenacen)
4. Previous surgery for BOO
5. Acute urinary retention in the 12 months prior to baseline

6. Urinary tract infection within 6 weeks prior to baseline
7. History of significant hypotensive episodes or symptoms of fainting, dizziness or lightheadedness
8. Unstable cardiovascular disease, particularly coronary artery disease, arrhythmias, atrial tachycardia, or congestive heart failure
9. Clinically significant central nervous system disease including: Parkinsons disease, multiple sclerosis, transient ischemic attack, stroke, seizure disorder, depression, or behavioural disturbances
10. History of peripheral vascular or cerebrovascular disease
11. History of narrow angle glaucoma or increased ocular pressure
12. Clinically significant gastrointestinal disorder (e.g., gastroparesis, constipation, diarrhoea, colitis, gastrointestinal tract obstruction, hiatal hernia with reflux oesophagitis, cholestasis).
13. History of clinically significant liver disease, e.g., hepatitis B
14. Prohibited medications taken within two weeks prior to baseline
15. Concomitant use of any agent that has a significant interaction with CYP3A4 or P glycoprotein (Pgp)
16. Clinically significant abnormalities in laboratory test results (including hepatic and renal panels, complete blood count [CBC], chemistry panel)
17. Participation in an investigational drug or device study within 30 days prior to screening
18. Concomitant urological disorders: bladder neck stenosis, urethral stricture, bladder stones, bladder diverticulum, recurrent urinary tract infections, neurogenic bladder
19. Diagnosed or suspected prostate cancer
20. Known hypersensitivity to anti-cholinergic agents
21. Unwillingness or inability to comply with the study protocol for any other reason
22. 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
23. Any clinically significant abnormality on 12-lead ECG

Date of first enrolment
01/07/2006

Date of final enrolment
31/03/2007

Locations

Countries of recruitment
United Kingdom

England

Germany

Ireland

Study participating centre

Plethora Solutions
London
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Sponsor information

Organisation
Plethora Solutions Limited (UK)

ROR
https://ror.org/02y9vw172

Funder(s)

Funder type
Industry

Funder Name
Plethora Solutions Limited (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration