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An open-label, escalating dose, proof of concept study to determine the effects of single oral doses of PSD506 on unstable urinary bladder contractions induced by volume provocation in subjects with detrusor hyper-reflexia secondary to spinal injuries above T12

Submission date
15/02/2007

Recruitment status
No longer recruiting

Registration date
20/04/2007

Overall study status
Completed

Last Edited
02/02/2017

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

Protocol serial number
PSD506-OAB-002

Study information

Scientific Title
An open-label, escalating dose, proof of concept study to determine the effects of single oral doses of PSD506 on unstable urinary bladder contractions induced by volume provocation in subjects with detrusor hyper-reflexia secondary to spinal injuries above T12

Study objectives
This study aims to establish the volume provocation test as a surrogate endpoint for demonstrating the efficacy of PSD506 on urinary bladder contractions. This study will also assess the safety of PSD506 in subjects with neurogenic detrusor overactivity due to a spinal cord injury, and will investigate the effect on detrusor instability and function in this patient group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Wandsworth Research Ethics Committee, 17/10/06,ref: 06/Q0803/161

Study design
This is an open-label, single-centre, escalating dose, proof of concept study of the effects of single doses of PSD506 on volume provocation tests in subjects with stable spinal injuries above T12.

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Detrusor hyper-reflexia secondary to spinal injury (mid-thoracic or cervical level)

Interventions
Single oral administration of PSD506 capsules 5 mg to 40 mg

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome(s)
To determine the effects of single oral doses of PSD506 (anti-muscarinic antagonist) on the reduction of unstable urinary bladder detrusor contractions induced by volume provocation testing in patients with hyper-reflexia secondary to spinal injury.

Key secondary outcome(s))
1. To assess the safety of PSD06 in this population
2. To determine the dose-response of different doses of PSD506 on the reduction of unstable urinary bladder detrusor contractions

Completion date
30/04/2007

Eligibility

Key inclusion criteria
1. Male or female subjects, aged 18 years or over
2. Spinal lesion above T12, which has been stable for at least 6 months prior to screening.
3. Detrusor hyper- reflexia secondary to spinal injury (mid-thoracic or cervical level) present for at least 12 months
4. If female, must either be surgically sterile or post-menopausal for the past year confirmed by a negative hormone panel (luteinizing hormone [LH], follicle stimulating hormone [FSH], 17β estradiol), or if of child-bearing potential be on adequate non-hormonal contraception (not oral or injectable) i.e. double barrier method or intrauterine contraceptive device [IUCD]. If male must also use adequate contraception (hormonal methods permitted)
5. Anti-muscarinic-naïve or treated subjects completing the 5 day wash-out period.
6. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. If female, has a positive urine pregnancy test
2. History of drug or alcohol abuse
3. Use of anti-muscarinic agents with a long-half life e.g. solifenacin.
4. Body Mass Index (BMI) greater than 28 or less than 16
5. Mean sitting BP greater than 150/85 or less than 100/60 mmHg
6. Mean HR greater than 90 bpm or less than 50 bpm
7. Clinically significant orthostatic hypotension present at screening
8. History of clinically significant hypotensive episodes or symptoms of fainting, dizziness, or lightheadedness
9. History or symptoms of cardiovascular disease, particularly coronary artery disease, arrhythmias, atrial tachycardia, or congestive heart failure

10. History of significant central nervous system disease, including: transient ischemic attack, stroke, seizure disorder, depression, or behavioral disturbances
11. History of peripheral vascular or cerebrovascular disease
12. History of narrow angle glaucoma or increased ocular pressure
13. Clinically significant bladder pathology, including urinary tract infection within 6 weeks of Day 0
14. History of diabetes
15. Clinically significant GI disorder which would, in the opinion of the investigator, pose an unacceptable risk to the subject in this study
16. History of clinically significant liver disease, e.g., hepatitis B
17. Prohibited medications taken within 2 weeks
18. Concomitant use of any agent that has a significant interaction with CYP3A4 or P glycoprotein (Pgp)
19. Clinically significant abnormalities in laboratory test results at screening (including hepatic and renal, full blood count, biochemistry and urinalysis)
20. Participation in an investigational drug or device study within 30 days prior to study.
21. Known hypersensitivity to anticholinergic agents
22. Concomitant disease or condition which could interfere with, or for which the treatment of might interfere with, the conduct of the study, or which 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. Unwillingness or inability to comply with the study protocol for any other reason.
24. Any clinically significant abnormality on 12-lead ECG

Date of first enrolment
01/09/2006

Date of final enrolment
30/04/2007

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Plethora Solutions
London
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Sponsor information

Organisation

Plethora Solutions Ltd (UK)

ROR
https://ror.org/02y9vw172

Funder(s)

Funder type
Industry

Funder Name
Plethora Solutions Ltd (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration