

A phase II, multi-centre, double-blind, placebo-controlled, 2-way cross-over study to evaluate efficacy, plasma concentrations and safety of 0.25 mL of 20 % w/w PSD503 for topical application in female volunteer patients with stress urinary incontinence

Submission date 15/02/2007	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 20/04/2007	Overall study status Completed	☐ Protocol
Last Edited 25/04/2014	Condition category Urological and Genital Diseases	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

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

Study information

Scientific Title

Study objectives

For many years alpha-adrenergic agonists have been used outside their approved use to treat SUI. As these medications are administered orally, the patients are subjected to systemic exposure so the applicability of these medications to certain patient groups e.g. those with cardiovascular disease, is limited due to the occurrence of sympathomimetic side-effects. Likewise systemic sympathetic side-effects may also limit patient compliance.

The purpose of the present study is to evaluate whether topical application of an alpha agonist on the anterior vaginal wall, over the site of the internal urethral sphincter and urethra can be efficacious in improving stress urinary incontinence (SUI), whilst minimising systemic exposure and hence adverse effects in the patient.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Guys Research Ethics Committee on 05/102005 (ref: 05/Q0704/136)

Primary study design

Interventional

Study design

This is a phase II, multi-centre, double-blind, placebo-controlled, 2-way cross-over study with subjects receiving each treatment once.

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Stress Urinary Incontinence (SUI)

Interventions

Single application of PSD503 gel containing an alpha-agonist or matching placebo.

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

PSD503

Primary outcome(s)

To evaluate efficacy of treatment with PSD503 compared with placebo in female volunteer patients with SUI as measured by the change in pad weight gain following the exercise stress pad test at pre-dose compared to the pad weight gain following the exercise stress pad test post-dose administration.

Key secondary outcome(s)

1. To evaluate plasma concentrations of PSD503 in female volunteer patients with SUI at 1 and 3 hours after dose administration
2. To evaluate changes in blood pressure and pulse after treatment with PSD503 compared with placebo in female volunteer patients with SUI over 3 hours after dose administration
3. To evaluate safety and tolerability of PSD503 compared with placebo in female volunteer patients with SUI

Completion date

31/07/2007

Eligibility**Key inclusion criteria**

1. Willing and able to provide written informed consent
2. Female and aged 18 - 75 years inclusive
3. SUI confirmed by a urinary (cough) stress test and urodynamic assessment within 36 months of Screening
4. SUI episode frequency ≥ 7 and ≤ 21 per week confirmed by a Frequency Volume Chart (FVC). If the subject has not completed a FVC prior to Screening, the subject will be asked to complete a FVC for a minimum of 3 days and to return this on Treatment Day 1
5. Normal filling cystometry conducted as part of a urodynamic assessment within 36 months of Screening (a bladder filling capacity of ≥ 300 mL and a first sensation of filling >100 mL)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Female

Key exclusion criteria

1. Has predominantly symptoms of urge urinary incontinence (>10 voids / 24 hours; >1 nocturia / night; urgency; urge incontinence) confirmed by a FVC. If the subject has not completed a FVC prior to Screening, the subject will be asked to complete a FVC for a minimum of 3 days and to return this on Treatment Day 1

2. Detrusor overactivity and / or a post-void residual volume >150 mL diagnosed by urodynamic examination within 36 months of screening
3. Unable to perform the physical exercises as required by the exercise stress pad test in the opinion of the Investigator
4. Current or past history of any cardiac abnormality or disease, or tachycardia, or any clinically significant abnormality in the opinion of the Investigator on electrocardiogram (ECG) at screening
5. Current or past history of hypertension (systolic blood pressure [SBP] ≥ 140 mmHg or a diastolic blood pressure [DBP] ≥ 90 mmHg). (If the subject has a SBP ≥ 140 mmHg or a DBP ≥ 90 mmHg on admission on any Treatment Day then they must be withdrawn)
6. Any significant medical history, including a current history of hyperthyroid disease, glaucoma, asthma or insulin dependent diabetes mellitus
7. Current or past history of (a) atherosclerotic disease including ischaemic heart disease, stroke, transient ischaemic attacks or with known aneurysm(s) or (b) vasospastic diseases e.g. Raynauds phenomenon and migraine
8. Known hypersensitivity to phenylephrine or any component in the preparation of PSD503 or has a known intolerance to sympathomimetics
9. Received within 4 weeks prior to screening or is continuing to receive any treatment which could:
 - a. Interact with phenylephrine (antihypertensives, atropine, monoamine-oxidase inhibitors [MAOIs], tricyclic antidepressants, selective serotonin reuptake inhibitors [SSRIs], serotonin / noradrenaline reuptake inhibitors [SNRIs], cyclopropane, halothane, sympathomimetics, cardiac glycosides, quinidine, doxapram, oxytocin, ergotamine, methysergide, dopexamine and entacapone)
 - b. Contain phenylephrine and related substances (e.g. Sudafed and Contac)
 - c. Cause phenylephrine-like side-effects
10. Received or is continuing to receive any treatment for SUI in the 4 weeks prior to screening (Subjects who have consistently performed Kegel exercises for at least 4 weeks prior to Screening and are committed to continue to perform them regularly throughout the study may participate).
11. Urogenital prolapse >grade 1, cystocele, or has a previous history resulting in scarring in the pelvic region (e.g. surgery / radiotherapy)
12. History of recurring proven urinary infections (i.e. more than 2 in past year) or cystitis or is known to be suffering from any sexually transmitted disease
13. Lactating, or pregnant or at risk of pregnancy during the study. The subject must be either using secure contraceptive precautions, or have been surgically sterilised or be post-menopausal (defined as at least two years since the last menstrual period)
14. History of alcohol or drug abuse
15. Any clinically significant findings on urinalysis, chemical pathology, physical examination, vital signs or clinically significant concurrent illness at screening that in the opinion of the Investigator precludes inclusion / further participation in the study
16. Participated in a clinical trial within 30 days of screening
17. Unable to read and/or understand English
18. Unwilling or unable to abide by the protocol or in the opinion of the investigator, a subject who is not likely to complete the study for any reason

Date of first enrolment

31/10/2005

Date of final enrolment

31/07/2007

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Plethora Solutions

London

United Kingdom

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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 Limited (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
	results				

[Results article](#)

01/12/2011

Yes

No