ISRCTN39853232 https://doi.org/10.1186/ISRCTN39853232

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

Registration date
20/04/2007

Overall study status
Completed

Last Edited
25/04/2014

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Miss Sheryl Caswell

Contact details
Plethora Solutions
Lupus House
11-13 Macklin Street
London
United Kingdom
WC2B 5NH
+44 (0)207 269 8630
sheryl.caswell@plethorasolutions.co.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PSD503-SUI-001

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)

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

Primary study design
Interventional

Secondary study design
Other

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
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.

Secondary outcome measures
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

Overall study start date
31/10/2005

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

Age group

Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
Up to 40 subjects may be recruited to obtain data on 30

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
England

United Kingdom

Study participating centre
Plethora Solutions
London
United Kingdom
WC2B 5NH

Sponsor information

Organisation
Plethora Solutions Ltd (UK)

Sponsor details
Lupus House
11-13 Macklin Street
London
United Kingdom
WC2B 5NH
+44 (0)207 269 8630
mail@plethorasolutions.co.uk

Sponsor type
Industry

Website
http://www.plethorasolutions.co.uk/index.php

ROR
https://ror.org/02y9vw172

Funder(s)

Funder type
Industry

Funder Name
Plethora Solutions Limited (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2011		Yes	No