ISRCTN57186091 https://doi.org/10.1186/ISRCTN57186091

The efficacy, safety and tolerability of PSD502 in subjects with premature ejaculation (PE)

Submission date	Recruitment status	[ ] Prospectively registered
13/01/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
27/03/2009	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
20/02/2019	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Carson Culley

Contact details
Department of Urology
University of North Carolina
Chapel Hill
North Carolina
United States of America
27599-7254
+1 919 966 2574
carson@med.unc.edu

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00556478

Secondary identifying numbers
PSD502

Study information

Scientific Title
A phase IIb, multicentre, randomised, double-blind, placebo-controlled study, with open-label follow on, to evaluate the efficacy, safety and tolerability of PSD502 in subjects with premature ejaculation (PE)

Study objectives
PSD502 is a metered dose spray containing a mixture of lidocaine and prilocaine which is under development by Plethora Solutions Ltd as a topical anaesthetic treatment for premature ejaculation (PE). The spray is applied to the glans penis a short time prior to intercourse. Most studies evaluating treatments for PE include intravaginal ejaculatory latency times (IELT) in the definition of PE. It has been estimated that PE affects 30 - 40% of the male population, but is paradoxically a condition for which they are least likely to seek help. Men with PE exhibit abnormal autonomic reflex pathways for the ejaculatory process. These include lower vibratory threshold to ejaculation, shorter bulbocavernous latency time and higher bulbocavernous evoked potentials. Reducing this heightened sensitivity of the glans with topical anaesthetics might therefore be a way of improving IELT, without adversely affecting the sensation of ejaculation.

Although IELT is an objective measure of ejaculatory function it does not address the impact of therapy on patients' well being and confidence in their sexual performance, which are important markers of treatment benefit. Therefore, if IELT is used as a sole efficacy measure it may not fully characterise the treatment benefit to the patient. For this reason in this study, a patient reported outcome (PRO) known as the Index of Premature Ejaculation will be used in conjunction with IELT to evaluate efficacy. Thus the combination of the objective measure of ejaculatory latency with the PRO of IPE should be able to provide efficacy data which are representative of clinical benefit to the patient.

The use of lidocaine, prilocaine and EMLA® cream as topical anaesthetics is well established. Many years of experience of use in large numbers of patients, as well as comprehensive non-clinical safety testing programs for various formulations of lidocaine and prilocaine exist, to support their safety and tolerability. This information, together with the clinical data from three studies with PSD502 (ANAE-059-00, PSD502-PE-001, and PSD502-PE-003), suggest that PSD502 may have beneficial effects in reducing penile sensation and prolonging IELT, and its use is unlikely to be associated with significant clinical safety or tolerability concerns.

The aim of this study is to provide additional placebo-controlled efficacy data to establish the clinical utility of PSD502 in the treatment of PE. In addition, long term open-label efficacy and safety data will be collected, to further support the registration package for PSD502 in the indication of treatment of PE.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Poland: Local Medical Ethics Committee (Komisja Bioetyczna Uniwersytetu Medycznego), 25 /09/2008, ref: R-I-002/281/2008
2. USA: Schulman Associates Institutional Board, 17/10/2008, ref: IRB # 07-4087-0
3. Canada: Trafalgar Ethics Board, 04/10/2008, ref: IRB# 07-023

Study design
Phase IIb multicentre randomised double-blind placebo-controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Premature ejaculation

Interventions
PSD502 is a metered dose aerosol spray that delivers a eutectic mixture of lidocaine and prilocaine. The placebo is a metered dose aerosol spray that is identical in appearance to PSD502 spray and contains the same propellant. Subjects will be randomised to PSD502 or placebo in a 2: 1 ratio. A single dose of PSD502 or placebo consist of three sprays applied to the glans penis. Subjects will continue for a three-month double-blind treatment followed by 5 months of open-label treatment.

Intervention Type
Drug

Phase
Phase II/III

Drug/device/biological/vaccine name(s)
PSD502 (containing lidocaine and prilocaine)

Primary outcome measure
Current information as of 28/01/2010:
To evaluate efficacy of treatment with PSD502 compared with placebo in subjects with PE as measured by:
1. Changes in mean IELT from baseline to during three-month double-blind treatment
2. Changes in all IPE domains from baseline to month three

Initial information at time of registration:
To evaluate efficacy of treatment with PSD502 compared with placebo in subjects with PE as

measured by:
1. Changes in mean IELT from baseline to during three-month double-blind treatment
2. Changes in selected IPE domains from baseline to month three

Secondary outcome measures
Current information as of 28/01/2010:
1. Proportion of subjects with short mean IELT during the three months of double-blind treatment
2. Relationship between IELT and IPE
3. Change in mean IELT from baseline
4. Subject and partner PEP scores
5. Evaluation of the safety and tolerability of PSD502 compared with placebo in subjects with PE as measured by adverse events (AE) and serious adverse events (SAE) data for both the subject and his sexual partner, collected throughout the study

Initial information at time of registration:
1. Change in selected IPE domains from baseline to three months
2. Proportion of subjects with short mean IELT during the three months of double-blind treatment
3. Relationship between IELT and IPE
4. Change in mean IELT from baseline
5. Subject and partner PEP scores
6. Evaluation of the safety and tolerability of PSD502 compared with placebo in subjects with PE as measured by adverse events (AE) and serious adverse events (SAE) data for both the subject and his sexual partner, collected throughout the study

Overall study start date
24/10/2007

Completion date
14/10/2009

Eligibility

Key inclusion criteria
Current information as of 28/01/2010:
A subject will be considered suitable for the study if he fulfills all of the following criteria:
1. Willing and able to provide written informed consent
2. Male, aged 18 years and over
3. Diagnosed with PE according to Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM-IV) crietria and International Society for Sexual Medicine (ISSM) definition
4. Diagnosed with lifelong PE
5. Acceptable response to screening Premature Ejaculation Profile (PEP)
6. Subject must be in a stable heterosexual and monogamous relationship and their partner must provide consent
7. Acceptable sexual encounters in the baseline period

Initial information at time of registration:
A subject will be considered suitable for the study if he fulfills all of the following criteria:
1. Willing and able to provide written informed consent
2. Male, aged 18 years and over

3. Diagnosed with PE
4. Acceptable response to screening Premature Ejaculation Profile (PEP)
5. Subject must be in a stable heterosexual and monogamous relationship and their partner must provide consent
6. Acceptable sexual encounters in the baseline period

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
256 total (103 in Poland)

Key exclusion criteria
A subject, or his sexual partner where stated, who fulfil any of the following criteria will be excluded from the study:
1. Subject, or his sexual partner, has received an investigational (non-registered) drug within 30 days of screening
2. Subject has erectile dysfunction
3. The subject, or his sexual partner, has a physical or psychological condition that would prevent them from undertaking the study procedures, including, but not limited to, the following:
3.1. Urological disease
3.2. Ongoing significant psychiatric disorder not controlled by medication
4. Subject has safety testing abnormalities at the screening visit
5. Subjects taking excluded medications or receiving any treatment for PE
6. Subject, or his sexual partner, has a current history of alcohol or drug abuse
7. The subject, or his sexual partner, is unlikely to understand or be able to comply with study procedures, for whatever reasons
8. Subject, or his sexual partner, has known drug sensitivity to amide-type local anaesthetics
9. Subjects with pregnant partners
10. Subject with sexual partners of child-bearing potential and not using appropriate contraception
11. Subject, or his sexual partner, has a history of glucose-6-phosphate dehydrogenase (G6PD) deficiency or use of medications that would increase susceptibility to methemoglobinaemia
12. Subject, or his sexual partner, uses class I (e.g. mexiletine, tocainide) or III (e.g. amiodarone, sotalol) anti-arrhythmic drugs

Date of first enrolment
24/10/2007

Date of final enrolment
14/10/2009

Locations

Countries of recruitment
Canada

Poland

United States of America

Study participating centre
University of North Carolina
North Carolina
United States of America
27599-7254

Sponsor information

Organisation
Plethora Solutions Ltd (UK)

Sponsor details
4th Floor, 233 High Holborn
London
United Kingdom
WC1V 7DN
+44 (0)20 3077 5400
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
Sciele Pharma, Inc (USA)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2010	20/02/2019	Yes	No