ISRCTN46090514 https://doi.org/10.1186/ISRCTN46090514

A phase II, multi-centre, randomised, double-blind, placebo-controlled, parallel group, proof of concept study to compare the efficacy, safety and tolerability of PSD502, delivered topically onto the upper vagina and cervix, to placebo in controlling discomfort/pain intensity in subjects undergoing outpatient hysteroscopy

Submission date
23/11/2007

Recruitment status
No longer recruiting

Registration date
13/02/2008

Overall study status
Completed

Last Edited
13/02/2008

Condition category
Signs and Symptoms

[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PSD502-UP-001

Study information

Scientific Title

Study objectives
Hysteroscopy is used extensively in the evaluation of common gynaecological problems such as premenopausal menstrual disorders, infertility and postmenopausal bleeding. It allows direct visualisation of the uterine cavity and the opportunity for targeted biopsy, safe removal of endometrial polyps, and treatment of submucous fibroids, septa and adhesions. There is a general consensus that hysteroscopy is the current gold standard for evaluating intrauterine pathology, including submucous myomas, polyps, hyperplasia and cancer.

This study aims to evaluate the efficacy of PSD502 in relieving discomfort/pain at placement of the tenaculum on the anterior lip of the cervix during outpatient hysteroscopy. Topically delivered agents have a theoretical advantage over cervical injection in terms of ease of administration and the potential for side effects with oral or systemically administered agents.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local ethics committee (Wojskowy Instytut Medyczny) on the 22nd August 2007 (ref: 121/WIM/2007).

Study design
A phase II, multi-centre, randomised, double-blind, placebo-controlled, parallel group, proof of concept study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Discomfort or pain during hysteroscopy

Interventions
Study medication (active or placebo) will be sprayed onto the cervix in 10 metered dose sprays (to give a total of 75 mg lidocaine and 25 mg prilocaine, or placebo). The first spray will be to the cervix, followed by each of the 4 vaginal fornices in clockwise fashion from the anterior fornix (anterior, left lateral, posterior, right lateral); the spraying pattern will be repeated immediately to complete 10 sprays in total. The time of final spray application will be recorded. After a minimum of 5 minutes and no more than 10 minutes, the excess fluid will be swabbed away. A tenaculum will then be used to secure the cervix and the hysteroscope will be inserted. The subject will then undergo the hysteroscopy procedure.

Product: PSD502 is a metered dose spray that delivers a eutectic mixture of lidocaine and prilocaine for topical anaesthesia. Each actuation dispenses 7.5 mg lidocaine and 2.5 mg prilocaine in their base forms. The propellant used in this spray is norflurane (HFA-134a), which also serves as a solvent. The spray provides a concentrated film of local anaesthetic base, which facilitates drug penetration and is capable of providing rapid, superficial anaesthesia of non-keratinised skin.

Dose: Ten metered dose sprays will be used to deliver a total dose of 75 mg lidocaine and 25 mg prilocaine.

Administration: Topical administration to the vagina and cervix approximately 10 minutes, but no sooner than 5 minutes, prior to hysteroscopy.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Lidocaine, prilocaine

Primary outcome measure
To evaluate the efficacy of PSD502 in relieving discomfort/pain at placement of the tenaculum on the anterior lip of the cervix assessed using a 100 mm VAPS in subjects undergoing hysteroscopy.

Secondary outcome measures
1. To evaluate the efficacy of PSD502 in relieving discomfort/pain during insertion of the hysteroscope as assessed using a VAPS in subjects undergoing hysteroscopy
2. To evaluate the efficacy of PSD502 in relieving discomfort/pain during examination of the uterine cavity as assessed using a VAPS in subjects undergoing hysteroscopy
3. To evaluate the efficacy of PSD502 in relieving the worst discomfort/pain experienced during the entire hysteroscopy procedure using a 4-point discomfort/pain scale
4. To evaluate the need for additional analgesia in the 24 hours after the procedure
5. To evaluate the safety and tolerability of PSD502 administered to the cervix and vagina

Overall study start date
03/01/2008

Completion date
13/03/2008

Eligibility

Key inclusion criteria
A subject will be invited to participate if she meets the following inclusion criteria:
1. Healthy, pre-menopausal female who requires hysteroscopy
2. Aged 18 - 50 years inclusive
3. Clinically insignificant medical history and clinical examination other than the underlying condition requiring treatment, in the opinion of the Investigator
4. Post menstruation, but prior to ovulation at the time of the procedure and has a negative pregnancy test
5. Able to understand and complete the visual analogue pain scale (VAPS) and 4-point discomfort /pain scale, in the opinion of the Investigator
6. Willing and able to provide written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
24

Key exclusion criteria
A subject will be excluded from study participation if she meets any of the following criteria:
1. Contraindication to hysteroscopy
2. Known hypersensitivity to amide-type local anaesthetics
3. Received another investigational product within the previous 3 months
4. Current history of alcohol or drug abuse such that the subject is unable to comply with the study procedures or has resulting clinically significant organ damage, in the opinion of the Investigator
5. Clinically-significant medical history or clinical finding (e.g. bleeding diathesis or coagulopathy) that would affect the subject's ability to take part in the study, in the opinion of the Investigator
6. Previous hysteroscopy with technical difficulties or side effects
7. Used lidocaine or prilocaine preparation within 6 hours before the hysteroscopy procedure

Date of first enrolment
03/01/2008

Date of final enrolment
13/03/2008

Locations

Countries of recruitment
Poland

Study participating centre
Department of Gynaecology
Warsaw
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Sponsor information

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Industry

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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