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Phase II, multicentre, randomised, double-blind, placebo-controlled, pilot study to determine the efficacy, safety, tolerability and pharmacokinetics of intravesical PSD597 in reducing the pain of the bladder biopsy procedure

Submission date	Recruitment status	[ ] Prospectively registered
25/09/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/10/2006	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
08/08/2008	Surgery	[ ] 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
PSD-PP-002

Study information

Scientific Title

Acronym
PSD597 Bladder Biopsy

Study objectives
Cystoscopies are often performed in the physician office using local anaesthesia in the form of 2% lidocaine gel which is squeezed through the urethra prior to insertion of the cystoscope. This results in anaesthesia of the urethra allowing passage of the cystoscope to be generally well tolerated. However, additional procedures beyond a visual diagnosis may not be possible as the local anaesthetic effect is limited to the urethra. Patients who are able to tolerate it do have bladder biopsies performed without anaesthesia but this procedure, though bearable, is painful. If a technique was available that allowed the anaesthetic effect to be extended beyond the urethral mucosa to the bladder mucosa and sub-mucosal space, it would be possible to carry out many more procedures in the office with a resulting reduction in cost and an increase in convenience and comfort to the patient.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ethical Review Committee, Inc. (USA), approval gained 17 August 2006.
2. The Queens University and Affiliated Teaching Hospitals, Health Sciences Human Research Ethics Board (REB) (Canada), review information pending

Study design
This is a phase II, multicentre, randomised, double-blind, placebo-controlled, parallel group, pilot 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
Persons scheduled to undergo a bladder biopsy

Interventions
This is a phase II, multicentre, randomised, double-blind, placebo-controlled, parallel group, pilot study to determine proof of efficacy, safety, tolerability and pharmacokinetics of intravesical PSD597 in reducing the pain of bladder biopsy in the conscious patient receiving no sedation or other analgesia or anaesthesia except urethral anaesthesia with 2% lidocaine gel.

1. A single dose of PSD597 or placebo will be instilled via urinary catheter and remain in the bladder for 15 minutes before being drained through the cystocope sheath. PSD597 consists of 200 mg lidocaine (as 5ml of 4% lidocaine) instilled into an empty bladder via a urinary catheter followed by 5 ml 8.4% sodium bicarbonate solution.

2. Placebo consists of 10 ml normal saline instilled as two 5 ml instillates via a urinary catheter.

Standard treatment if discontinued from study.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
PSD597 (consists of 200 mg lidocaine as 5ml of 4% lidocaine)

Primary outcome measure
To assess the change in bladder pain between baseline and immediately after the first bladder biopsy achieved by PSD597 versus placebo.

Secondary outcome measures
1. To assess the change in bladder pain between baseline and different aspects of the procedure following treatment with PSD597 versus placebo.
2. To assess the safety and tolerability of PSD597 dosed intravesically prior to bladder biopsy.
3. To measure systemic exposure to lidocaine following intravesical PSD597 in patients undergoing bladder biopsy.

Overall study start date
18/09/2006

Completion date
01/01/2007

Eligibility

Key inclusion criteria
1. Males or Female aged over 18 years
2. Women of child bearing potential or men with partners of child bearing potential willing to commit to the use of a reliable form of contraception during the course of the study (e.g.

contraceptive pill or condoms)
3. Able to understand and complete the Visual Analogue Pain Score (VAPS) form
4. Provide written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40, to ensure 30 patients complete the study.

Key exclusion criteria
1. Receipt of another investigational product within one month prior to screening
2. Known hypersensitivity to amide-type local anaesthetics
3. Requirement for amide local anaesthetics pre-operatively other than 2% lidocaine for urethral anaesthesia prior to insertion of the cystocope
4. Clinically relevant abnormality on Electrocardiogram (ECG), such as prolonged QTc
5. History of alcohol or drug abuse within the past two years for which treatment has not been received
6. Clinically significant abnormal blood biochemistry or haematology
7. History of psychiatric illness, from vulnerable groups, or have learning difficulties
8. Female subjects who are pregnant or lactating
9. Presence of bladder, urethral, or ureteral calculi
10. Have taken an analgesic prior to the procedure (within specified time limits)
11. Known liver disease, known renal disease or heart-failure
12. Clinical evidence of urethritis
13. Urinary infection that has not resolved by Day one

Date of first enrolment
18/09/2006

Date of final enrolment
01/01/2007

Locations

Countries of recruitment
Canada

United States of America

Study participating centre
3822 Summit Street
Kansas City, Missouri
United States of America
64111

Sponsor information

Organisation
Plethora Solutions Ltd (UK)

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Sponsor type
Industry

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http://www.plethorasolutions.co.uk

ROR
https://ror.org/02y9vw172

Funder(s)

Funder type
Industry

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