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 protocolNot provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

- 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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

Plethora Solutions Ltd (UK)

ROR

https://ror.org/02y9vw172

Funder(s)

Funder type

Industry

Funder Name

Plethora Solutions Ltd (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration