

# 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

<b>Submission date</b> 25/09/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 12/10/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 08/08/2008	<b>Condition category</b> Surgery	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

**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

### Primary study design

Interventional

### Study design

This is a phase II, multicentre, randomised, double-blind, placebo-controlled, parallel group, pilot study.

### 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 cystoscope 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 cystoscope
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)

**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