

# A study to compare bladder function of healthy Asian and Caucasian women

<b>Submission date</b> 10/08/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 26/10/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 18/01/2012	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**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**

# Study information

## Scientific Title

### Study objectives

Fundamental physiological differences in bladder physiology exist between women of Caucasian and Asian origin.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Approved by Nottinghamshire Local Research Ethics Committee on the 16th April 2007 (ref: 07/Q2404/25)

### Study design

Prospective observational cohort study.

### Primary study design

Observational

### Secondary study design

Cohort study

### Study setting(s)

Other

### Study type(s)

Other

### Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

### Health condition(s) or problem(s) studied

Urinary incontinence

### Interventions

Single urodynamic investigation with urethral pressure profile measurement.

### Intervention Type

Other

### Phase

Not Specified

### Primary outcome measure

Mean bladder capacity in the two ethnic groups.

### **Secondary outcome measures**

The following will be compared between the two ethnic groups:

1. Differences in mean residual volume
2. Maximum urinary flow rate
3. Average flow rate
4. Bladder volumes at defined sensations (first sensation of filling)
5. Detrusor pressure rise during filling
6. Detrusor pressure generated during voiding
7. Maximum urethral closure pressure
8. Functional urethral length

### **Overall study start date**

01/06/2007

### **Completion date**

31/05/2008

## **Eligibility**

### **Key inclusion criteria**

1. Women of South Indian Asian or Caucasian ethnic origin (self-specified)
2. Willing to undergo urodynamic assessment

### **Participant type(s)**

Patient

### **Age group**

Not Specified

### **Sex**

Female

### **Target number of participants**

70

### **Key exclusion criteria**

1. History of urinary tract infection within 3 months
2. History of recurrent urinary tract infection (3+ episodes in 12 months)
3. Previous pregnancy beyond 12 weeks gestation
4. Currently pregnant
5. Previous gynaecological or urological surgery (not including termination of first trimester pregnancy)
6. History of urinary tract abnormality
7. History of detrusor overactivity, childhood bedwetting
8. Current use (within 3 weeks) of anticholinergic medication, duloxetine or other drug with effects upon the urinary tract

### **Date of first enrolment**

01/06/2007

**Date of final enrolment**

31/05/2008

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Reproductive Science Section**

Leicester

United Kingdom

LE2 7LX

## **Sponsor information**

**Organisation**

University of Leicester (UK)

**Sponsor details**

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**Sponsor type**

University/education

**Website**

<http://www.le.ac.uk>

**ROR**

<https://ror.org/04h699437>

## **Funder(s)**

**Funder type**

Industry

**Funder Name**

UCB Pharma 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?
<a href="#">Results article</a>	results	01/07/2005		Yes	No