

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

Submission date 10/08/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 26/10/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 18/01/2012	Condition category 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

Contact name
Dr Douglas Tincello

Contact details
Reproductive Science Section
Cancer Studies and Molecular Medicine
Robert Kilpatrick Clinical Sciences Building
Leicester Royal Infirmary
PO Box 65
Leicester
United Kingdom
LE2 7LX
+44 (0)116 252 5813
dgt4@le.ac.uk

Additional identifiers

Protocol serial number
UHL 10288 v1.1

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

Study type(s)

Other

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(s)

Mean bladder capacity in the two ethnic groups.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Female

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

United Kingdom

England

Study participating centre

Reproductive Science Section

Leicester

United Kingdom

LE2 7LX

Sponsor information

Organisation

University of Leicester (UK)

ROR

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

Funder(s)

Funder type

Industry

Funder Name

UCB Pharma Ltd (UK)

Results and Publications

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?
Results article	results	01/07/2005		Yes	No