# Effect of patient's position on the results of urodynamic investigation

Submission date 30/09/2005	<b>Recruitment status</b> No longer recruiting	<ul> <li>Prospectively registered</li> <li>Protocol</li> </ul>
<b>Registration date</b> 30/09/2005	<b>Overall study status</b> Completed	<ul> <li>[] Statistical analysis plan</li> <li>[X] Results</li> </ul>
<b>Last Edited</b> 28/06/2010	<b>Condition category</b> Urological and Genital Diseases	Individual participant data

### Plain English summary of protocol

Not provided at time of registration

### **Contact information**

**Type(s)** Scientific

**Contact name** Dr Ami Shukla

#### **Contact details**

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### Additional identifiers

EudraCT/CTIS number

**IRAS number** 

ClinicalTrials.gov number

Secondary identifying numbers N0162147172

### Study information

#### Scientific Title

#### **Study objectives**

The research question is based on the null hypothesis, that the supine or sitting position of the patient does not make any difference to the results of urodynamic investigation.

**Ethics approval required** Old ethics approval format

**Ethics approval(s)** Approved by the local research ethics committee

**Study design** Randomised controlled trial

**Primary study design** Interventional

**Secondary study design** Randomised controlled trial

Study setting(s) Hospital

**Study type(s)** Other

Participant information sheet

Health condition(s) or problem(s) studied

Urinary incontinence

#### Interventions

Randomised, cross-over study where each participant will serve as their own control by being randomised into one of two groups.

1. Group 1 will have the urodynamics performed first in a lying position followed by a sitting position

2. Group 2 will have the urodynamic performed first in a sitting position followed by a lying position

Intervention Type Other

**Phase** Not Applicable

Primary outcome measure

1. Whether the position makes any difference in the results of the urodynamic study

2. Whether the women find one position better/more comfortable/less embarrassing over the other, or is there no preference from the women's perspective

#### Secondary outcome measures

Not provided at time of registration

**Overall study start date** 01/06/2004

Completion date 30/11/2004

## Eligibility

#### Key inclusion criteria

All women referred for urodynamic studies for incontinence to the urogynae department. 50 volunteers are required for the study, aged at least 18 years.

Participant type(s) Patient

**Age group** Adult

**Lower age limit** 18 Years

**Sex** Female

**Target number of participants** 50

**Key exclusion criteria** Does not match inclusion criteria

**Date of first enrolment** 01/06/2004

Date of final enrolment 30/11/2004

### Locations

**Countries of recruitment** England

United Kingdom

**Study participating centre Clinical Fellow Urogynaecology** Northampton United Kingdom NN1 5BD

### Sponsor information

**Organisation** Department of Health

#### Sponsor details

Richmond House 79 Whitehall London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

**Sponsor type** Government

Website http://www.dh.gov.uk/Home/fs/en

### Funder(s)

Funder type Government

**Funder Name** Northampton General Hospital NHS Trust (UK) - NHS R&D Support Funding

### **Results and Publications**

**Publication and dissemination plan** Not provided at time of registration

Intention to publish date

**IPD sharing plan summary** Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Results article</u>	results	01/05/2006		Yes	No