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

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

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
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
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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

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	01/05/2006		Yes	No