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# Target-controlled sedation versus 'low-dose' spinal anesthesia in tension-free suburethral sling surgery for stress incontinence.

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 12/09/2003 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 12/09/2003 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 24/11/2011 | Urological and Genital Diseases | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Dr Philip Toozs-Hobson

**Contact details**
Birmingham Women's Hospital
Uro-gynaecology Department
Edgbaston
Birmingham
United Kingdom
B15 2TG
+44 (0)121 472 1377 ext 4707

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
N0047111207

# Study information

### Scientific Title

### Acronym
NN/A

### Study objectives
We propose a randomised, double-bind study to compare both anaesthetic techniques (target-controlled sedation and 'low-dose' spinal anaesthesia).

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Not provided at time of registration

### Study design
Randomised double-bind study

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Treatment

### Participant information sheet

### Health condition(s) or problem(s) studied
Urological and Genital Diseases: Stress incontinence

### Interventions
Each volunteer will be studied for the duration of the operation, until completion of the post-operative questionnaire and urodynamic studies, 3 h postoperatively. The average length of the procedure is 45 min. The only additional invasive procedure that would not be part of the routine is the subcutaneous local anaesthetic injection of 2 ml Lignocaine 1% in the back of the volunteers randomised into the propofol target controlled sedation group for the purpose of blinding.

### Intervention Type
Other

### Phase

Not Specified

### Primary outcome measure
Outcomes will be assessed by indices of patient satisfaction, satisfaction for surgical conditions, perioperative sedation scores, oxygenation, haemodynamic variables and the impact of anaesthetic technique on return of bladder sensation.

### Secondary outcome measures
Not provided at time of registration

### Overall study start date
01/06/2002

### Completion date
30/09/2006

## Eligibility

### Key inclusion criteria
Patients will be recruited from the clinical gynaelogical practice of Mr P Toozs-Hobson and Mr Emens. Individuals scheduled for suburethral sling surgery will be invited to participate in the investigation. Written consent will be obtained in all cases. We aim to recruit 25 patients to each arm of the study.
Inclusion criteria: first operative procedure for stress incontinence.

### Participant type(s)
Patient

### Age group
Not Specified

### Sex
Female

### Target number of participants
50

### Key exclusion criteria
1. Contradiction to spinal anaesthesia
2. Unable/unwilling to give consent
3. Significant respiratory/cardiovascular disease/epilepsy
4. Allergy to propofol, opioids and local anaesthetics

### Date of first enrolment
01/06/2002

### Date of final enrolment
30/09/2006

## Locations

**Countries of recruitment**
England

United Kingdom

**Study participating centre**
**Birmingham Women's Hospital**
Birmingham
United Kingdom
B15 2TG

# Sponsor information

**Organisation**
Department of Health (UK)

**Sponsor details**
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

**Sponsor type**
Government

**Website**
http://www.doh.gov.uk

# Funder(s)

**Funder type**
Government

**Funder Name**
Birmingham Women's Healthcare NHS Trust (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? |
|---|---|---|---|---|---|
| Results article | results | 01/07/2010 | | Yes | No |