ISRCTN64888483 https://doi.org/10.1186/ISRCTN64888483

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
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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