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 [] Statistical analysis plan Registration date Overall study status 12/09/2003 Completed [X] Results [] Individual participant data Last Edited Condition category **Urological and Genital Diseases** 24/11/2011

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

Protocol serial number 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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s))

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Female

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

United Kingdom

England

Study participating centre Birmingham Women's Hospital

Birmingham United Kingdom B15 2TG

Sponsor information

Organisation

Department of Health (UK)

Funder(s)

Funder type

Government

Funder Name

Birmingham Women's Healthcare NHS Trust (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	01/07/2010		Yes	No