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A pilot study comparing general versus spinal anaesthesia for vaginal surgery

Submission date	Recruitment status	[_] Prospectively registered
09/02/2012	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/03/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/04/2016	Surgery	

Plain English summary of protocol

Background and study aims
The purpose of this study is to examine the effect of anaesthetic technique (spinal or general anaesthesia) on the outcomes of vaginal surgery. Currently both forms of anaesthetic are in common practice with no knowledge of which is the best way to anaesthetise patients when having this surgery. Gynaecological vaginal surgery for urinary incontinence or vaginal prolapse is very common; some estimate that 11% of all women will have a prolapse operation by the age of 80. Knowledge of the right sort of anaesthetic may therefore help inform a large number of people on safety and side effects.

Who can participate?
All women who are undergoing vaginal surgery for prolapse or incontinence in our institution are eligible to participate. There are no age restrictions.

What does the study involve?
The study involves participants being randomly allocated to either a general or spinal anaesthetic and then taking part in an assessment of a number of factors. Participants will assess pain control before the operation, at 2 and 24 hours after surgery and at 2, 6 and 12 weeks following surgery using a visual chart. We will assess postoperative pain relief requirements as a secondary pain measure. We will also look at any complications of each anaesthetic technique, time of return to normal function, outcome of the operative procedure and patient satisfaction using a questionnaire that will be posted to participants.

What are the possible benefits and risks of participating?
The benefit of participating is to help inform patients of the future. Both techniques are in common and safe usage already so there are no extra risks involved. The risks are therefore those of anaesthesia already in use. These include nausea and vomiting, sore throat, backache, residual sleepiness and headache, need for intraoperative interventions, intraoperative pain, need for intraoperative sedation, and failure to establish a satisfactory spinal block and/or need to convert to general anaesthesia, or difficulty in establishing an airway.

Where is the study run from?
The study is run from the University Hospital of North Staffordshire in the UK.

When is the study starting and how long is it expected to run for?
It is anticipated it will run for one year commencing February 2012.

Who is funding the study?
It is being funded by a grant from the North Staffordshire Medical Institute, UK.

Who is the main contact?
Mr Jason Cooper
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Contact information

Type(s)
Scientific

Contact name
Mr Jason Cooper

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
01

Study information

Scientific Title
A pilot study comparing general versus spinal anaesthesia for vaginal surgery: a randomised controlled trial

Acronym
GOSIP

Study objectives
There is no difference in postoperative outcomes with either spinal or general anaesthesia in gynaecological pelvic surgery.

Ethics approval required

Old ethics approval format

Ethics approval(s)
NRES Committee West Midlands, 01 July 2011 ref: 11/WM/0044

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to requesta patient information leaflet

Health condition(s) or problem(s) studied
Anaesthesia in gynaecological pelvic surgery

Interventions
Spinal or general anaesthesia

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
Postoperative pain assessed by 100mm visual analogue scale (VAS) performed at preoperative baseline, at 2 and 24 hours after surgery and at 2, 6 and 12 weeks following surgery

Secondary outcome measures
1. Possible complications of anaesthetic technique
2. Time to return to normal function will include postoperative recovery room stay, time to fitness for hospital discharge and SF 36 questionnaire at 12 weeks (compared to a preoperative baseline)
3. Surgical outcome will be assessed by comparing results on the Vaginal Symptoms Questionnaire at 12 weeks with preoperative baseline

Overall study start date
01/02/2012

Completion date
01/02/2013

Eligibility

Key inclusion criteria
All women undergoing vaginal surgery for incontinence or prolapse, no age criteria, all patients eligible

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
80

Key exclusion criteria
1. Lack of capacity to give consent
2. Inability to read and write English

Date of first enrolment
01/02/2012

Date of final enrolment
01/02/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospital of North Staffordshire
Stoke-on-Trent
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ST4 6QG

Sponsor information

Organisation
University Hospital of North Staffordshire (UK)

Sponsor details
R&D Department
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Sponsor type
Hospital/treatment centre

Website
http://www.uhns.nhs.uk

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
North Staffordshire Medical Institute (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	01/08/2015		Yes	No