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A study to investigate the effect of heating and humidifying laparoscopic insufflation gas on post laparoscopic pain

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 27/09/2012	**Condition category** Signs and Symptoms	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N0084113224

Study information

Scientific Title

Study objectives
The aim of the study is to find out if women will have less pain after their laparoscopy if the gas used during the operation is not as dry and contains more water.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Signs and Symptoms: Pain

Interventions
1. CO2 unheated and unhumified
2. CO2 heated but unhumified
3. CO2 unheated but humified
4. CO2 heated and humified

The surgeon, patient and main researcher will be blinded and only the anaesthetist will be aware of the gas used. In all cases the gas will be collected when the peritoneum is decompressed after surgery and the volume and water content measured as an estimate of water loss.

Post operative pain will be assessed using a visual response scale at 1, 2, 3 h and the evening of the operation and also the first, second and seventh day post laparoscopy. Responses will be requested for pain at the site of the wounds, pain in the pelvis and shoulder tip pain.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Post-operative shoulder tip pain.

Key secondary outcome(s))
Analgesia used and the length of time taken to return to normal activities.

Completion date
01/12/2005

Eligibility

Key inclusion criteria
Women undergoing laparoscopic surgery for sterilisation or tubal patency testing will be given the opportunity to participate in the study. Subjects will be randomly allocated to one of the four groups.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Female

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
31/01/2002

Date of final enrolment
01/12/2005

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Hull and East Yorks Hospital Trust
Hull
United Kingdom
HU8 9HE

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
The North and South Bank Research and Development Consortium (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration