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

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	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
27/09/2012	Signs and Symptoms	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
Post-operative shoulder tip pain.

Secondary outcome measures
Analgesia used and the length of time taken to return to normal activities.

Overall study start date
31/01/2002

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

Age group
Not Specified

Sex
Female

Target number of participants
Not provided at time of registration

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
England

United Kingdom

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

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
The North and South Bank Research and Development Consortium (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