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Low rate versus high rate insufflation of the peritoneal cavity for laparoscopic surgery: a randomised comparative study

Submission date 29/09/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 29/09/2006	**Overall study status** Completed	
Last Edited 24/09/2013	**Condition category** Surgery	

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
N0453168841

Study information

Scientific Title

Study objectives
This study aims to find out whether the low rate and high rate of CO2 insufflation at the commencement of laparoscopic surgery have different effects on cardiac function.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised comparative 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
Surgery: Laparoscopy

Interventions
The study involves insufflating the abdomen with gas at either a low rate or high rate and evaluating its impact on the efficacy of the heart pump and on the hormones released during surgery. It will be a randomised clinical study involving 2 groups (CO2 insufflation at 1 l/1min & CO2 insufflation of 18 l/min)

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
CO2

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
19/07/2005

Completion date
30/12/2005

Eligibility

Key inclusion criteria
Consenting adult patients aged 16-80 years

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
19/07/2005

Date of final enrolment
30/12/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
MRI Central Manchester & Manchester Children's University Hospitals
Manchester

United Kingdom
M13 9WL

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
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Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Central Manchester and Manchester Children's University Hospitals NHS Trust (UK) - Trust Endowment,

Funder Name
NHS R&D Support Funding

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