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 |
| Registration date | Overall study status | [] Statistical analysis plan |
| 29/09/2006 | Completed | [_] Results |
| Last Edited 24/09/2013 | Condition category Surgery | Individual participant data |
| | | [] 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 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 London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

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