ISRCTN44438769 https://doi.org/10.1186/ISRCTN44438769

Port fixity during laparoscopic surgery; a randomised comparison of cutting and blunt induction of secondary ports

Submission date 29/09/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 29/09/2006	**Overall study status** Completed	
Last Edited 30/04/2010	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr Basil Ammori

Contact details
MRI Central Manchester & Manchester Children's University Hospitals
Manchester Royal Infirmary
Oxford Road
Manchester
United Kingdom
M13 9WL
+44 (0)161 276 3510
basil.ammori@cmmc.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0453168843

Study information

Scientific Title

Study objectives
To compare cutting and conical mechanisms for port induction with regard to port fixity to the abdominal wall during laparoscopic surgery.

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)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Surgery: Laparoscopy

Interventions
Group 1: 5mm and 10mm ports with cutting trocars and smooth shaft
Group 2: 5mm and 10mm ports with conical trocars and smooth shaft

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure

The traction required to partially withdraw the secondary 5mm and 10mm port from the abdominal wall is measured using purpose designed device. The measurements will be taken at the beginning of surgery and every 30mins thereafter until completion of the operation.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/05/2003

Completion date
01/05/2005

Eligibility

Key inclusion criteria
50 patients will be consented and the study will compare 50 5mm ports and 50 10mm ports in each group.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/05/2003

Date of final enrolment
01/05/2005

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

Funder Name
Trust (UK) 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2007		Yes	No