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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

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Additional identifiers

Protocol serial number
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

Study type(s)
Not Specified

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(s)
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.

Key secondary outcome(s))
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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
United Kingdom

England

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

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

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

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