

Cost-effectiveness of surgical simulation

Submission date 29/10/2010	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 20/12/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 11/05/2017	Condition category Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr Rajesh Aggarwal

Contact details
Department of Surgery and Cancer
10th Floor, QEQM Building
St Mary's Hospital Campus
Imperial College London
Praed Street
London
United Kingdom
W2 1NY

Additional identifiers

Study information

Scientific Title

An evaluation of the cost-effectiveness of virtual reality surgical simulation to shorten the learning curve for real laparoscopic procedures

Study objectives

Surgical trainees who are simulator-trained to proficiency in basic laparoscopic skills shall proceed at a more rapid rate along their learning curve for real laparoscopic procedures.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Prospective randomised controlled clinical trial

Primary study design

Interventional

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Laparoscopic surgery

Interventions

The LapMentor™ virtual reality surgical simulator shall be used for training the intervention group in laparoscopic technical skills, under the guise of an evidence-based training curriculum.

The training arm will undergo a training curriculum. This will be in three phases, i.e.:

1. Knowledge - a structured knowledge-based online training and assessment tool (including text, diagrams and video)
2. Technical skills - a step-wise, structured and proficiency-based virtual reality training curriculum (incorporating technical skills, procedural tasks and full procedures)
3. Attitudes - a one-day session in the simulated OR to perform two complete laparoscopic cases with a full operative team. This will be scheduled in the simulated operating room.

The control arm will not undergo any of the above.

The duration of treatment for the training arm will be approximately two weeks. The duration of follow-up for each subject (i.e., both arms of the trial) will be approximately 2 months.

Intervention Type

Procedure/Surgery

Phase

Not Applicable

Primary outcome(s)

1. Procedure time taken (for intra-abdominal part of procedure), measured during the operative intervention
2. Quality of operative procedure by Global Rating Scale, measured within one week of the operative intervention

Key secondary outcome(s)

1. Knowledge (multiple-choice test), measured within two weeks of recruitment to the study for the control group, and within two weeks of completion of the training curriculum for the intervention group

2. Attitudes (surgical team measurements, i.e. NOTTS and OTAS), measured during operative intervention
3. Clinical - death, deep vein thrombosis or pulmonary embolism, re-intervention (percutaneous, endoscopic or surgical), blood transfusion, unplanned ITU/HDU admission, failure to be discharged within 30 days, bile duct injury within 30 days of intervention

Completion date

31/01/2012

Eligibility

Key inclusion criteria

1. Specialist general surgery trainee doctors, i.e. ST1 through to ST5
2. Have performed less than 50 laparoscopic cases (i.e. appendicectomy and cholecystectomy) as primary operator

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Subjects who have participated in a simulator-based training curriculum for laparoscopic surgery.

Date of first enrolment

01/02/2011

Date of final enrolment

31/01/2012

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Department of Surgery and Cancer
London
United Kingdom
W2 1NY

Sponsor information

Organisation

Imperial College London and Imperial College Healthcare NHS Trust (UK)

ROR

<https://ror.org/041kmwe10>

Funder(s)

Funder type

University/education

Funder Name

Imperial College London (UK) - Department of Surgery and Cancer

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration