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Cost-effectiveness of surgical simulation

Submission date 29/10/2010	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 20/12/2010	**Overall study status** Completed	
Last Edited 11/05/2017	**Condition category** Surgery	

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
01/02/2011

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

Age group
Adult

Sex
Both

Target number of participants
30 surgeon operators

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
England

United Kingdom

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)

Sponsor details
c/o Lucy Parker
Research Governance Manager
AHSC Joint Research Office
G02, Sir Alexander Fleming Building
South Kensington Campus
London
England
United Kingdom
SW7 2AZ

Sponsor type
Hospital/treatment centre

Website
http://www.imperial.ac.uk/clinicalresearchgovernanceoffice

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

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