

# Cost-effectiveness of surgical simulation

<b>Submission date</b> 29/10/2010	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 20/12/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 11/05/2017	<b>Condition category</b> 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

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## 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

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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