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Do medical students learn laparoscopic (keyhole) surgery skills more quickly when they train using a robotic camera holder rather than a human camera holder?

Submission date
04/03/2019

Recruitment status
No longer recruiting

Registration date
08/08/2019

Overall study status
Completed

Last Edited
01/09/2020

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
In keyhole (laparoscopic) surgery, the aim is to avoid making large openings in a patient's body. The surgeons insert a camera and thin tools into small holes to view the inside of the patient's body and perform the surgery. The aim of this research is to find out whether trainee surgeons can perform keyhole (laparoscopic) surgery techniques more quickly if a robot holds the camera rather than a human. The robotic holder might provide a more steady camera image.

Who can participate?
Trainee surgeons who are following the European School of Urology's training curriculum, European training in Basic Laparoscopic Urological Skills (E-BLUS). Students with previous experience of laparoscopic skills will be excluded from the study.

What does the study involve?
Trainees will be randomly allocated to the robot or human camera holder and will carry out the practice surgery tasks in a simulated set-up. The time taken to complete the tasks will be recorded.

What are the possible benefits and risks of participating?
Participants will benefit from this trial in improving their keyhole surgery skills. They may experience stress and fatigue due to the demands of surgical training.

Where is the study run from?
The trial will take place at the Sherman Education Centre, Guy’s Hospital, London.

When is the study starting and how long is it expected to run for?
December 2018 to June 2019

Who is funding the study?
FreeHand Surgeon (UK), the maker of the Freehand robotic holder system.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
N/A

Study information

Scientific Title
Evaluation of FreeHand camera holder on the learning curve for basic laparoscopic skills using the European training in basic laparoscopic urological skills (E-BLUS) validated curriculum

Acronym
ROBLAP

Study objectives
The Robotic Arm will make the learning curve steeper or remain the same compared with conventional methods.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/02/2019, BDM Research Ethics Panel (Franklin Wilkins Building, 5.9 Waterloo Bridge Wing, Waterloo Rd, London SE1 9NH; +44 207 848 4020; rec@kcl.ac.uk) ref: LRU-18/19-10406

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Surgical education

Interventions
Participants will be recruited on a voluntary basis. An open invitation will be sent out to medical students at King's College London. This invitation will be issued via GKT Medical School Association newsletters, Facebook group pages e.g. KCL Surgical and KCL Urological societies, and word of mouth. Students will have to sign up via an online form. Students with previous experience of laparoscopic skills will be excluded from the study.

Two cohorts will be created via randomization: Control (conventional human assistant) and Intervention (FreeArm robotic laparoscopic holder). Each cohort will have 20 students. They will complete the four trials of the EBLUS curriculum: peg transfer, cutting a circle, needle guidance, laparoscopic suturing.

After enrollment participants are invited to an orientation session to help them understand the basics of keyhole surgery and equipment. Inductions sessions are 2 hours in length. After this participants are invited to attend training sessions at our simulation laboratory where they will conduct basic keyhole surgery tasks on simulators. Training consists of 10 sessions with each session lasting between 1-3 hours depending on how long they take to complete the tasks. Both cohorts are are assessed by the time it takes for them to successfully complete the task; this is done by a stopwatch. Participants from the two cohorts are free to attend training sessions as and when it suits them.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
FreeHand laparoscopic camera holder

Primary outcome(s)
Time taken to complete the training tasks measured using a stopwatch

Key secondary outcome(s))
N/A

Completion date
28/06/2019

Eligibility

Key inclusion criteria
1. Medical student
2. No previous laparoscopic training

Participant type(s)
Health professional

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
40

Key exclusion criteria
1. Previous laparoscopic experience
2. Unable to commit to course
3. Consent not given

Date of first enrolment
27/02/2019

Date of final enrolment
17/06/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Guy's Hospital
Great Maze Pond
London
United Kingdom
SE1 9RT

Sponsor information

Organisation
King's College London

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Industry

Funder Name
FreeHand Surgeon

Results and Publications

Individual participant data (IPD) sharing plan
Consent has been obtained from participants to store and analyze anonymous data. Raw data will be stored with trial organisers on secure systems and can be available on request. Ethical approval does allow for the distribution of raw data. Processed data will be available via publication.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2020	01/09/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes