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Comparing laparoscopic and robotic surgical training and operative skills

Submission date
17/09/2019

Recruitment status
No longer recruiting

Registration date
13/11/2019

Overall study status
Completed

Last Edited
01/12/2022

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
Minimally invasive surgery (keyhole surgery) traditionally uses the laparoscopic technique. Laparoscopic skills are difficult to acquire and take years of practice for junior surgeons to go through the learning curve to be able to perform operations safely. More recently, the robotic technique is being used for operations, which may be easier and quicker for junior surgeons to learn basic surgical skills. The aim of this study is to compare the ability of junior surgeons and medical students to perform basic surgical skills after one day's training on either the laparoscopic or robotic simulator.

Who can participate?
Junior surgical trainees and medical students

What does the study involve?
Each participant spends two days at The Newcastle Surgical Training Centre. They are randomly allocated to either the laparoscopic or robotic group. Each participant spends 6 hours training on the laparoscopic or robotic simulator. The following day they perform three different operations on cadaveric specimens. These involve surgical skills such as suturing and careful handling of tissue. The operating is recorded and timed. Two consultant surgeons then score the anonymised participant using video analysis. They are given a global rating scale score for each procedure and the number of suturing errors is recorded.

What are the possible benefits and risks of participating?
The students and trainees who take part will gain 2 days of practice in minimally invasive surgical skills. This is very sought after amongst those interested in a career in surgery and usually requires a high fee payment for a surgical skills course. All participants will benefit substantially. Those in the laparoscopic group will benefit from training in a skill used by their team and them on a daily basis. Those in the robotic group will have the experience of this new technique, which is extremely unlikely that they would otherwise have access to this in their usual training facilities. There are no risks of participating.

Where is the study run from?
Newcastle Surgical Training Centre (UK)

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

Who is funding the study?
Intuitive Foundation (USA)

Who is the main contact?
Prof. Long Jiao
l.jiao@imperial.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Long Jiao

Contact details
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
LJ006

Study information

Scientific Title
Shortening surgical training through robotics: a randomised controlled trial of laparoscopic versus robotic surgical learning curves

Study objectives

To determine whether there are any differences in surgical skills between laparoscopic and robotic operating on cadaveric specimens after simulation training for both surgical trainees and medical students.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Newcastle Surgical Training Centre is licensed to train students on human cadavers (Human Tissue Act 2004, Licensing no: 12148). Ethics approval was not required as there are no patients involved in the trial.

Study design
Randomised parallel-group trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available

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

Interventions
Surgical trainees from the North-West Thames London Deanery and the North-East Deanery in the UK, as well as medical students from Imperial College London and from Newcastle University, will be invited to participate. Each participant will spend two days at The Newcastle Surgical Training Centre. The participants will be invited to the centre and blinded to their group until the training day. Eligible participants will be computer randomised in a 1:1 ratio between laparoscopic and robotic training. Both groups will receive either 6 hours robotic or laparoscopic simulation and box-training followed by 2 hours recorded cadaveric operating (three different operations) the following day. These involve surgical skills such as suturing and careful handling of tissue. The operating will be recorded and timed. Two consultant surgeons will then score the anonymised participant using video analysis. they will be given a global rating scale score for each procedure and the number of suturing errors will be recorded.

Intervention Type
Behavioural

Primary outcome measure

Global rating score (maximum points 30) for each operative task

Secondary outcome measures
1. Time taken for each task (minutes) measured after each operative task
2. Number of suturing errors for each operative task, measured after each operative task
3. Number of loops created with continuous suture closure of gastrostomy (cohort 1), measured after closure of gastrostomy
4. Number of completed sutures in 40 minutes (cohort 2), measured after completion of operative task
5. Surgeon comfort following all procedures, measured on a scale of 1-5 after completion of operative tasks

Overall study start date
01/01/2019

Completion date
01/06/2019

Eligibility

Key inclusion criteria
1. Surgical trainees (ST):
1.1. UK surgical trainee
1.2. Knowledge of anatomy and steps of cholecystectomy
2. Medical students (MS):
2.1. UK medical student year 3-5

Participant type(s)
Health professional

Age group
Adult

Sex
Both

Target number of participants
20

Key exclusion criteria
1. Surgical trainees (ST):
1.1. Surgical trainee for more than 4 years
1.2. Performed >5 laparoscopic or robotic cholecystectomies as the primary surgeon
2. Medical students (MS):
2.1. Previous assisting in minimally invasive surgery

Date of first enrolment
01/03/2019

Date of final enrolment

01/05/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Newcastle Surgical Training Centre
United Kingdom
NE7 7DN

Sponsor information

Organisation
The Cromwell Hospital

Sponsor details
London Robotic HPB Centre
164-178 Cromwell Road
Kensington
London
England
United Kingdom
SW5 0TU
+44 (0)2074605700
umeer.waheed@nhs.net

Sponsor type
Hospital/treatment centre

Website
https://www.bupacromwellhospital.com

ROR
https://ror.org/0465c2k31

Funder(s)

Funder type
Charity

Funder Name
Intuitive Foundation

Results and Publications

Publication and dissemination plan
The researchers plan to publish the results in a high-impact peer-reviewed international surgical journal and to present the results of the study at international surgical conferences. They plan to submit for publication at the end of 2019.

Intention to publish date
01/06/2020

Individual participant data (IPD) sharing plan
The datasets generated and analysed will be available upon request from Tamara Gall (tamara.gall1@nhs.net). The data will be available from June 2019 for a 12-month period after which it will be deleted. The data will be stored on a password-protected NHS computer. The data will only be shared with a high impact peer-reviewed journal if requested during the review process. Consent was obtained for data collection by all participants, all data is anonymised with participants recorded as a number with no personal identification.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			05/12/2019	No	No
Basic results		07/06/2020	11/06/2020	No	No
Results article		02/12/2020	01/12/2022	Yes	No