STUDY PROTOCOL:

A randomised controlled trial of laparoscopic versus robotic surgical learning curves

Study Management Group

Principal Investigator: Professor Long Jiao

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Sponsor

The London Robotic HPB Centre is the main research Sponsor for this study. For further information regarding the sponsorship conditions, please contact umeer.waheed@nhs.net or proflongjiao.hpb@gmail.com .

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Intuitive Foundation

This protocol describes the '**A randomised controlled trial of laparoscopic versus robotic surgical learning curves'** study and provides information about procedures for entering participants. Every care was taken in its drafting, but corrections or amendments may be necessary. These will be circulated to investigators in the study. Problems relating to this study should be referred, in the first instance, to the Principal Investigator.

This study will adhere to the principles outlined in the UK Policy Frame Work for Health and Social Care Research It will be conducted in compliance with the protocol, Data Protection Act 2018 and General Data Protection Regulations (Europe) and other regulatory requirements as appropriate.

1. INTRODUCTION

1.1 Background

The past three decades have witnessed the rapid emergence of minimally invasive surgery (MIS) which has led to a total re-evaluation of conventional surgical approaches across all specialties. The advantages of MIS over open operations is clearly established with patients experiencing less pain, less blood loss and a faster return to functional activities. The first acknowledged laparoscopic cholecystectomy was performed in 1987(1) since which the laparoscopic technique has become the standard worldwide for many operations including: cholecystectomy(2); appendicectomy(3); and, in the United Kingdom (UK), up to 74% of all colorectal cancer resections are now performed laparoscopically (UK National Bowel Cancer Audit).

However, there has been a slower drive to widely embrace these techniques in some specialties, particularly for long operations and for those involving complex anastomoses in specialties such as hepato-pancreato-biliary and vascular surgery. Barriers to establishing laparoscopic practice including: operator discomfort and fatigue; physiological tremors which are amplified through the length of the instruments; and limited instrument motion; have limited the use of these techniques in complex cases and prevented their widespread adoption. Further, laparoscopic surgery requires a significant amount of time and training before competency in basic skills is reached. Even following laparoscopic proficiency in experienced surgeons, there is a further steep learning curve for individual operations. Indeed, the number of cases after which operative time and morbidity is reduced may be as high as 85 for laparoscopic colectomy(4); 100 for laparoscopic urological procedures(5); and 104 for laparoscopic pancreaticoduodenectomy(6).

These inherent challenges led to robotic solutions. In 2000, the Da Vinci robotic system (Intuitive Surgical Inc., Mountain View, CA) gained FDA-approval(7). Robotic surgery has several advantages to the normal laparoscopic approach. It provides a three-dimensional visual field with depth perception. Its ‘wristed’ instruments provide the natural seven degrees of motional freedom mimicking open surgery. These advances increase dexterity and improve hand-eye coordination. The learning curve for robotic operations may be shorter than the conventional laparoscopic approach across surgical specialties (8) (9) (10) (11) (12) (13).

1.2 Study Rationale

This study is designed to establish whether the acquisition of minimally invasive surgical skills, including suturing and basic operations, differ between robotic and laparoscopic

techniques in novice surgeons and in the surgically naïve. We aim to assess the surgical competence of operators to compare the length of training time required for laparoscopic and robotic surgery.

2. 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.

Primary outcome:

- The global rating score (GRS) for each procedure

Secondary outcomes:

- Time taken for each procedure
- Number of suturing errors for each procedure
- Number of loops created with continuous suture closure of gastrostomy (surgical trainee group)
- Number of completed sutures in 40 minutes (medical student group)
- Surgeon comfort following all procedures
- Surgeon fatigue following all procedures

3. STUDY DESIGN

Design and Randomisation

This trial is a randomised, parallel-group trial investigating laparoscopic versus robotic training in junior surgical trainees and medical students. 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. 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 (Randomisation performed by TMHG). Both groups will receive either 6 hours robotic or laparoscopic simulation and box-training followed by 2

hours recorded cadaveric operating the following day. The trial will be conducted at the Newcastle Surgical Training Centre, The Freeman Hospital, Newcastle, UK. The Newcastle Surgical Training Centre is licensed to train students on human cadavers (Human Tissue Act 2004, Licensing no: 12148).

Recruitment:

Flyers will be distributed in surgical departments to recruit surgical trainees and medical students to the trial. The prospective participants will be given an NHS email address to contact if interested in participating in the trial. All participants will be given written information and consent forms to sign before proceeding with the trial

Duration of study:

We aim to complete the study within 2 months. Participants will be recruited over a two month period prior to the start of the trial. We aim to recruit 20 surgical trainees and 20 medical students to the trial

4. PARTICIPANT RECRUITMENT

4.1 Pre-recruitment evaluations

No requirements that a participant must fulfil

4.2 Inclusion Criteria

- Surgical trainees (ST)
    - UK surgical trainee
    - Knowledge of anatomy and steps of cholecystectomy
- Medical students (MS)
    - UK medical student year 3-5

4.3 Exclusion Criteria

- Surgical trainees (ST)
    - Surgical trainee for more than 4 years
    - Performed >5 laparoscopic or robotic cholecystectomies as the primary surgeon
- Medical students (MS)
    - Previous assisting in minimally invasive surgery

4.4 Withdrawal Criteria

A participant may withdraw from the study at any point. They will be able to contact Tamara Gall by email or telephone or in person on the days of the trial to confirm their withdrawal at any time. If the participant withdraws before the cadaveric operating then their data will not be used in the study. A consort flow diagram will be created to show any participant withdrawals.

5. ADVERSE EVENTS

5.1 Definitions

Adverse Event (AE): any untoward occurrence in a participant.

Serious Adverse Event (SAE): any untoward and unexpected occurrence or effect that:

- **Results in death**
- **Is life-threatening** – *refers to an event in which the subject was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe*

- **Requires hospitalisation**
- **Results in persistent or significant disability or incapacity**

5.2. Reporting Procedures

All adverse events should be reported. Any questions concerning adverse event reporting should be directed to the Principal Investigator in the first instance.

5.2.1 Non serious AEs

All such events, whether expected or not, should be recorded.

5.2.2 Serious AEs

An SAE form should be completed and emailed to the Principal Investigator within 24 hours.

6. ASSESMENT AND FOLLOW UP

There will be no follow-up required following the participant involvement in the trial

7. REGULATORY ISSUES

7.1 Consent

Consent to enter the study will be sought from each participant after a full explanation has been given, an information leaflet offered and time allowed for consideration. Signed participant consent will be obtained. The right of the participant to refuse to participate without giving reasons must be respected. All participants are free to withdraw at any time.

7.2 Confidentiality

The Principal Investigator will preserve the confidentiality of participants taking part in the study and fulfil transparency requirements under the General Data Protection Regulation for health and care research. Data and all appropriate documentation will be stored for a minimum of 10 years after the completion of the study, including the follow-up period.

7.3 Sponsor

The London Robotic HPB Centre will act as the main Sponsor for this study

7.4 Funding

Intuitive Foundation are funding this study. All participants will be reimbursed travel and accommodation expenses

8. STUDY MANAGEMENT

The day-to-day management of the study will be co-ordinated through Tamara Gall.

9. PUBLICATION POLICY

The study will be submitted for publication to a peer-reviewed international surgical journal.

10. REFERENCES

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