Participant Information Sheet

Validity and reliability of intraoperative objective laparoscopic rectal cancer performance assessment tools in residency training

You are being invited to take part in a research project. Your participation is entirely voluntary. Before you decide whether you wish to participate, you must understand why the research is being done and what it will involve. You do not have to make an immediate decision.

What is the purpose of the study?

This study is investigating two bespoke objective performance assessment tools designed to measure intraoperative performance of laparoscopic rectal resection. Both have been successfully applied at the specialist level and within randomised trials but there is no data in training settings. This study will assess the face, clinical and predictive validity of the tools as well as their ability to define learning curves and track progress of 50 UK, Australasian and US trainees across one year.

This study is entirely observational. All perioperative care, surgical technique and involvement of trainees with each case remains with the responsible local clinicians.

Why have I been chosen?

You are being asked to participate in this research as you are a colorectal surgical trainee expecting to perform laparoscopic rectal resections and have declared an interest in this study.

What will I have to do if I take part?

If you agree to take part in the study, you will be asked to sign a consent form and provide basic details of prior experience. You will then be allocated anonymised study ID.

After all eligible laparoscopic rectal resectional cases that you perform (independent or supervised) between October 2019 and September 2020, you will need to complete two brief objective performance assessment tools and collect basic 30-day patient outcome data. Your trainer will complete the forms as well. They will then need to be sent to your local co-ordinating office.

These assessments will not be used for any purpose other than this research. Specifically, they will not be used by your trainers or training board in any way. All established trainee assessment methods and requirements for progress remain unchanged and remain under the control of each respective training system.

Participant incentives

The success of this study is dependent on the completion of the tools. Given this additional paperwork and the importance of capturing consecutive cases, a small incentive payment of £20/$A35/$25 per case is available to trainees to maximise the return rate. This requires return of complete trainee and trainer forms with 30 day post-operative data.

In keeping with UK research governance requirements as well as international transfer considerations, payments will be in the form of gift certificates. Trainees can select from a list of retailers. Each trainee may receive a maximum of 10 payments in this study. Additional case submission is strongly encouraged but will not attract further payments.

PubMed citable collaborative authorship is offered to trainees and trainers as a further incentive.

What are the possible disadvantages of taking part?

We do not anticipate that there will be additional disadvantages to you from taking part in this study. Previous experience has confirmed short tool completion times. The study data is limited to readily available pathological and 30 day outcome data and is not expected to be a burden.

Will my taking part in the study be kept confidential?

All paperwork relating to you will be labelled only with a unique research study number. It will be impossible for anyone to identify you. Your performance will not be identifiable in any reports or publications resulting from this study. Study data will be securely stored for 5 years following study completion, after which time they will be destroyed.

Who has reviewed the study?

UK NHS Research Ethics Committee approval (ref: 19/LO/1440).

What will happen to the results of the study?

Results of the trial will be submitted to Surgical Endoscopy in keeping with the funding contract as well as conference presentations. PubMed citable collaborative authorship is offered.

If you have any further questions or concerns regarding this project, please contact:

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