

Validation of a novel porcine polypectomy trainer

Submission date 26/10/2011	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 10/02/2012	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 24/01/2020	Condition category Surgery	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Background and study aims:

The WIMAT colonoscopy suitcase is a simulator designed to teach trainee doctors how to perform colonic polypectomy (the removal of polyps in the colon to prevent them from turning cancerous). The Simbionix GI Mentor™ is a Virtual Reality (VR) simulator that is also used to teach colonic polypectomy. Evidence suggests that those who train on the Simbionix GI Mentor perform better in the early phase of real colonoscopy training. However, this type of skills transfer has not been previously demonstrated for the WIMAT colonoscopy suitcase. The aims of this study are to assess whether using the WIMAT colonoscopy simulator results in skills transfer to the clinical setting, and to compare the level of skills transfer attained using the two simulators.

Who can participate?

ST3-7 level trainees in General Surgery or Gastroenterology who have performed 1-20 'real life' endoscopic procedures and less than five colonic polypectomies.

What does the study involve?

Participants are randomly allocated to either WIMAT colonoscopy suitcase training or VR training. They attend 3 (1 hour) sessions of standardised self-directed learning on their assigned simulator over 3 weeks (one per week). The skills of the two groups are compared after 3 and 6 months.

What are the possible benefits and risks of participating?

Improved training in colonic polypectomy may improve patient outcomes.

Where is the study run from?

Welsh Institute for Minimal Access Therapy (UK)

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

December 2011 to August 2013

Who is funding the study?

Royal College of Surgeons of England (UK)

Who is the main contact?
James Ansell

Contact information

Type(s)
Scientific

Contact name
Mr James Ansell

Contact details
Welsh Institute for Minimal Access Therapy (WIMAT)
Cardiff Medicentre
Heath Park
Cardiff
United Kingdom
CF14 4XN

Additional identifiers

Protocol serial number
Awaiting

Study information

Scientific Title
Validation of a novel porcine polypectomy trainer: a randomised controlled validation study

Study objectives
Can a novel colonic polypectomy simulator develop transfer skills for use in colonoscopy?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled validation study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Training surgeons

Interventions

The cohort of trainees are divided into groups according to their previous experience in colonoscopy. Then their videoed performance will be measured on the colonoscopy trainer. This will tell us if the trainer is able to distinguish between levels of expertise.

The most novice group is randomised into two further groups. One will receive simulator training and the other standard training. The skills of each group will be compared to evaluate the overall use of the course in training.

Intervention Type

Procedure/Surgery

Phase

Not Applicable

Primary outcome(s)

Transfer of skills

Key secondary outcome(s)

Performance indicators

Completion date

01/08/2013

Eligibility

Key inclusion criteria

1. Trainees specialising in general surgery or gastroenterology
2. Consultant colorectal surgeons and gastroenterologists

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

20

Key exclusion criteria

1. Any trainee who has performed more than 5 previous colonic polypectomies
2. Any trainee who has observed or taught on the advanced colonoscopy course at WIMAT

Date of first enrolment

01/12/2011

Date of final enrolment

01/08/2013

Locations

Countries of recruitment

United Kingdom

Wales

Study participating centre

Welsh Institute for Minimal Access Therapy (WIMAT)

Cardiff

United Kingdom

CF14 4XN

Sponsor information

Organisation

Welsh Institute for Minimal Access Therapy (WIMAT), Cardiff University

ROR

<https://ror.org/03kk7td41>

Funder(s)

Funder type

Research organisation

Funder Name

Royal College of Surgeons of England (UK)

Alternative Name(s)

RCS England, RCS ENG, The Royal College of Surgeons of England, RCS

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary