

Validation of a novel porcine polypectomy trainer

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| Submission date 26/10/2011 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 10/02/2012 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 24/01/2020 | Condition category Surgery | <input type="checkbox"/> Individual participant data <input type="checkbox"/> 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)
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised controlled validation study

Primary study design
Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

Transfer of skills

Secondary outcome measures

Performance indicators

Overall study start date

01/12/2011

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

Age group

Adult

Sex

Both

Target number of participants

50

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

Sponsor details

c/o Mr James Ansell

Cardiff Medicentre

Heath Park
Cardiff
Wales
United Kingdom
CF14 4XN

Sponsor type

Hospital/treatment centre

Website

<http://www.cardiff.ac.uk/pgmde/sections/wimat/>

ROR

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

Funder(s)

Funder type

Research organisation

Funder Name

Royal College of Surgeons of England (UK)

Alternative Name(s)

RCS

Funding Body Type

Private sector organisation

Funding Body Subtype

Associations and societies (private and public)

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

2014 results in thesis <https://orca.cf.ac.uk/64961/2/2014anselljmd.pdf>

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration