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Assessment of proficiency based simulation training on resident performance on Laparoscopic Salpingo-Oophrectomy

Submission date
20/06/2013

Recruitment status
No longer recruiting

Registration date
02/07/2013

Overall study status
Completed

Last Edited
18/07/2013

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
The integration of laparoscopic techniques combined with the changing model of resident work hours and increased focus on patient safety have made it necessary for residents to obtain a greater variety of technical skills with less exposure. There are few studies in obstetrics and gynecology assessing the role of simulation laboratories (allows residents to learn and apply clinical skills in a safe and supportive environment before applying these skills in the clinical setting) on resident education. The studies that are published focus on training inexperienced surgeons and have found an improvement in participants performance after undergoing simulation training. We propose to study a technically more difficult procedure to better assess the role of simulation on both beginner and experienced resident performance on intermediate level surgery.

Who can participate?
Obstetrics and Gynecology (OBGYN) residents at the University of Pennsylvania will be able to participate. All female patients in the department of Gynecology who is undergoing a Laparoscopic Salpingo-Oophorectomy will be allowed to participate.

What does the study involve?
The study involves the assessment of surgical performance of the participating residents in the operating room. The residents will be randomly allocated to two groups. Half the residents will undergo a simulation training program after completing their first live procedure, half will continue with the standard training model. All the participating residents will perform a second live procedure in the operating room. The residents will be evaluated again using the global rating scale. A comparison will be made on resident proficiency in performing a Laparoscopic Salpingo-Oophorectomy between those that had the simulation training and those that did not.

What are the possible benefits and risks of participating?
Resident subjects may benefit from simulation training through increased access to the simulation laboratory. Patient safety may improve, as residents will have the opportunity to practice laparoscopy in a simulated environment prior to the operating room. The participants

are not under any risk. The patients will undergo the routine Laparoscopic Salpingo-Oophorectomy as they were consented for.

Where is the study run from?
Hospital of the University of Pennsylvania and the Pennsylvania Hospital.

When is the study starting and how long is it expected to run for?
The study will take place over the academic year of 2013-2014.

Who is funding the study?
The Simulation tools will be provided by the Penn Center for Simulation and funded by the University of Pennsylvania.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
818211

Study information

Scientific Title
Assessment of proficiency based simulation training on resident performance on Laparoscopic Salpingo-Oophrectomy: a prospective randomized controlled trial

Study objectives

The hypothesis states that surgical trainees who are simulator-trained to proficiency in basic and intermediate laparoscopic skills shall proceed at a more proficient level along their learning curve for real laparoscopic procedures.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board, University of Pennsylvania, Office of Regulatory Affairs, Approved June 13, 2013

Study design
Prospective randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

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
Laparoscopic surgery

Interventions
The training arm will perform a live Laparoscopic Bilateral Salpingo-Oophorectomy in the operating room. They will then undergo a training curriculum using the LapMentor™ virtual reality surgical simulator, under the guise of an evidence-based training curriculum.
This will be in three phases, i.e.:
1. Knowledge - a structured knowledge-based online training and assessment tool (including text, diagrams and video)
2. Technical Skills - a step-wise, structured and proficiency-based virtual reality training curriculum (incorporating technical skills, procedural tasks and full procedures)
3. Attitudes - a one-day session in the simulated OR to perform two complete laparoscopic cases with a full operative team. This will be scheduled in the simulated operating room.
This group will then perform a second live laparoscopic Bilateral Salpingo-Oophorectomy in the operating room.

The control arm will perform two live laparoscopic Salpingo-Oophorectomy in the operating room. They will then have the opportunity to complete the simulation training curriculum.

Both groups will be evaluated in the operating room with a global rating scale. A statistical analysis will be performed at the end.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
Score on Objective Structured Assessment of Technical Skill (OSAT) tool, a global rating scale. Measurements will be made at the end of the study using statistical analysis.

Secondary outcome measures
Resident satisfaction, resident confidence after first and second laparoscopic procedure. Measurements will be made at the end of the study using statistical analysis.

Overall study start date
26/06/2013

Completion date
26/06/2014

Eligibility

Key inclusion criteria
Obstetrics and Gynecology (OBGYN) Residents at the University of Pennsylvania
1. Novice- have completed less than ten cases of laparoscopic Bilateral Salpingo-Oophorectomy
2. Intermediate- have completed 10-100 cases of laparoscopic Bilateral Salpingo-Oophorectomy
3. All Residents that volunteer from the University of Pennsylvania, Male and Female, all ages.

Patients undergoing a laparascopic Bilateral Salpingo-Oophorectomy
Patients: Any Female who consented for the procedure listed, all ages accepted

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
96 (32 Physicians, 64 patients)

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment

26/06/2013

Date of final enrolment
26/06/2014

Locations

Countries of recruitment
United States of America

Study participating centre
3701 Market street, 3rd floor
Philadelphia
United States of America
19103

Sponsor information

Organisation
University of Pennsylvania (USA)

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Sponsor type
University/education

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http://www.uphs.upenn.edu/obgyn/research/ccr.htm

ROR
https://ror.org/00b30xv10

Funder(s)

Funder type
University/education

Funder Name
University of Pennsylvania (USA)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration