

Resident surgical laparoscopic salpingectomy training: a randomized controlled trial

Submission date 18/06/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 09/07/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 07/08/2019	Condition category Surgery	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

This study investigates whether a single session of practicing surgical techniques on a porcine (pig) cadaver improves Ob-Gyn resident (medical student) surgical skills.

Who can participate?

All PGY-1 through PGY-4 Ob/Gyn residents at Christiana Care Hospital.

What does the study involve?

Participants are randomly allocated into one of two groups. Those in group 1 (intervention) attend a session involving pre-session reading, a lecture, viewing a procedural video and then practicing a surgical procedure (laparoscopic salpingectomy) on a porcine cadaver. Those in group 2 (control) receive traditional training. All participants undergo on-site assessment and training (OSAT) before and after the training session. They are also asked to fill in surveys before and after the session to assess their comfort levels.

What are the possible benefits and risks of participating?

A potential benefit of the study is that simulation may improve surgical technique.

Where is the study run from?

Christiana Care Hospital, Newark (USA)

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

December 2013 to January 2014

Who is funding the study?

Christiana Care Hospital, Newark (USA)

Who is the main contact?

Dr Nima Patel

Contact information

Type(s)

Scientific

Contact name

Dr Nima Patel

ORCID ID

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Contact details

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19707

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

CCC #33254

Study information

Scientific Title

Traditional versus simulation resident surgical laparoscopic salpingectomy training: a randomized controlled trial

Study objectives

We conducted a randomized controlled trial to examine whether a single session of simulated practice of surgical techniques utilizing a porcine cadaver improved Ob-Gyn resident surgical skills. The study's primary hypothesis was formal training including video observation followed by a single session of procedural simulation in a porcine cadaver model would improve laparoscopic salpingectomy performance compared with traditional training methods.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Christiana Care Hospital Institutional Review Board, 11/29/2013, ref: CCC #33254

Study design

Single blinded (evaluator) single center 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 contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Traditional versus simulation resident surgical laparoscopic salpingectomy training

Interventions

1. The intervention group participated in a training module of assigned pre-session reading on pelvic anatomy from a gynecology textbook and a designated article on ultrasonic energy and a formal 3 hour simulation session. The simulation session included a 40-minute didactic introduction reviewing indications for, and the benefits of, laparoscopic salpingectomy and review of relevant anatomy and analogous structures between human and porcine models. It also outlined the fundamental steps of laparoscopic salpingectomy; reviewed the advanced Bipolar or ultrasonic energy sources used; and a video review of a simulated porcine model laparoscopic salpingectomy performed at our institution. Following this didactic presentation, participants had 60 minutes to familiarize themselves with and practice using instrumentation. Participants were then paired to each engage in a 30-minute simulation of laparoscopic tubal salpingectomy on a porcine cadaver model. During this time, each trainee performed a unilateral salpingectomy on the model. An experienced laparoscopist was present to give direction and feedback to participants during the simulation session to facilitate their training in instrumentation and on procedure performance.
2. The control group was not assigned any of the reading, educational activities or simulation session of the intervention group. They continued standard residency training of surgical skills.

Intervention Type

Procedure/Surgery

Primary outcome measure

The primary outcomes are the OSAT scores, based on a multi-item assessment that measures 9 aspects of surgical technique. Each item is rated from 1-5 using a Likert scale where 1 signifies a low and 5 a high score. For this study, the minimum score on the OSAT was 5 and the maximum achievable score was 45. This instrument has acceptable internal reliability (there was a single evaluator) and its validity is supported through correlations with conceptually related measures from a previously validated surgical skills Global Rating Scale.

Secondary outcome measures

Resident comfort level with laparoscopic surgical salpingectomy

Overall study start date

19/12/2013

Completion date

13/01/2014

Eligibility

Key inclusion criteria

All PGY-1 through PGY-4 Ob/Gyn residents at Christiana Care Hospital

Participant type(s)

Health professional

Age group

Adult

Sex

Both

Target number of participants

22

Total final enrolment

22

Key exclusion criteria

Unable to complete OSAT evaluation

Date of first enrolment

19/12/2013

Date of final enrolment

13/01/2014

Locations

Countries of recruitment

United States of America

Study participating centre

Christiana Care Hospital

4755 Ogletown-Stanton Rd.

Room 1903

Newark

United States of America

19718

Sponsor information

Organisation

Christiana Care Health System

Sponsor details

4755 Ogletown-Stanton Rd., Suite 1905, Dept of OB/GYN
Newark
United States of America
19707

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/02h905004>

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

Christiana Care Hospital, Newark (USA)

Results and Publications**Publication and dissemination plan**

The study has been presented at the 2014 Advancing Minimally Invasive Gynecology meeting. It is planned to publish the results in an internationally available refereed gynecology or medical education journal.

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2016	07/08/2019	Yes	No