Comparing hands-on training and video tutorial to hands-on training alone in teaching IUD application to 5th year medical students

Submission date 23/03/2015	Recruitment status No longer recruiting	Prospectively registered
		Protocol
Registration date	Overall study status	Statistical analysis plan
23/04/2015	Completed	Results
Last Edited	Condition category	Individual participant data
06/08/2020	Other	Record updated in last year

Plain English summary of protocol

Background and study aims

All medical students at the University of Helsinki are taught how to Insert a intrauterine device (IUD) as a part of the general gynecology course. The procedure is taught in a small group session, and includes a brief introduction presenting the technique and hands-on practice with the help of an applicator and plastic uterus-model. The aim of the study is to test whether or not an additional teaching resource, a video tutorial showing a IUD being inserted, could help students to learn this new skill and increase their self-confidence. This, in turn, may also improve the patient's experience of the procedure.

Who can participate?

Fifth-year medical students of the University of Helsinki, Finland.

What does the study involve?

The participants are allocated to either a control group or an intervention group. Those in the control group are taught using traditional hands-on training only. Those in the intervention group are taught using both traditional hands-on training and the video tutorial. The learning outcome is measured at the teaching session. This is done by an experienced teacher, the student and the patient with the help of structured questionnaires; these include an evaluation of the technical performance and questions on feelings of anxiety, communicative skills and pain. The results are compared between the control and the intervention group.

What are the possible benefits and risks of participating?

For the patient the risks of taking care in this study would be that the procedure might possibly take more time than normal and possibly more painful than normal since the inserter is a student without any previous experience of inserting an IUD. The benefits though are that the procedure is supervised by a very experienced gynecologist and teacher. In Finland, IUDs are mostly inserted by GPs that don't have as much experience of the procedure as our teacher. This ensures that the IUD is correctly inserted in the patients of our study.

Where is the study run from? Department of Obstetrics and Gynecology, Helsinki University Hospital and University of Helsinki (Finland).

When is the study starting and how long is it expected to run for? February 2015 to May 2015.

Who is funding the study? Investigator initiated and funded.

Who is the main contact? Dr Sabrina Forsell.

Contact information

Type(s)

Public

Contact name

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Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Comparing hands-on training and video tutorial to hands-on training alone in teaching IUD application to 5th year medical students: a single-center interventional study

Study objectives

Learning of IUD application is better when a video tutorial is added to traditional hands-on training.

Ethics approval required

Old ethics approval format

Ethics approval(s)

No ethics approval needed. Patients in the study have already agreed to be patients at a training session regardless of taking part in the study or not. This study is a study where these patients and the students fill in a questionnaire anonymously. No information is sought from patient records. Helsinki University ethics board for research in gynecology, pediatrics and psychiatry, was consulted on the need of ethics approval.

Study design

The study is a single-center interventional study. The intervention is a students teaching intervention consisting of a video tutorial. The patients receive the same care.

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

Health condition(s) or problem(s) studied

Teaching of intrauterine contraceptive device (IUD) application to medical students at the University of Helsinki as a part of the general gynecology course.

Interventions

The study intervention is teaching the application of an IUD with the additional resource of a video tutorial, showing a live situation of IUD insertion. The study design is a case-control study. The participants of the study are 80 fifth-year medical students of the University of Helsinki, divided into one control group and one intervention group. The former is taught using

traditional hands-on training only, whereas the latter receives both traditional hands-on training and the video tutorial. The patients are recruited from primary-care units. All patients receive the same treatment, that is application of an IUD (copper or hormonal).

Intervention Type

Behavioural

Primary outcome measure

The learning outcome is measured at the teaching session. The evaluation is done by an experienced teacher, the student and the patient with the help of structured questionnaires, including evaluation of the technical performance and questions on feelings of anxiety, communicative skills and pain. The results will be compared between the control and the intervention group.

Secondary outcome measures

The study has no secondary outcome measures.

Overall study start date

17/02/2015

Completion date

29/05/2015

Eligibility

Key inclusion criteria

- 1. 5th year medical students performing their basic gynecological course during 2015.
- 2. The patients are recruited from primary-care units for the teaching session. They are women that desire an IUD as contraception or as treatment for menstrual irregularities or dysmenorrea. They are recruited in the study at the session.

Participant type(s)

Mixed

Age group

Adult

Sex

Both

Target number of participants

160 (80 medical students and 80 patients)

Key exclusion criteria

Other than participants of the basic gynecology course. There are no exlusion criteria for the patients when it comes to parity or age.

Date of first enrolment

17/02/2015

Date of final enrolment

29/05/2015

Locations

Countries of recruitment

Finland

Study participating centre

Department of Obstetrics and Gynecology, Helsinki University Hospital and University of Helsinki

Haartmaninkatu 2

PL 140

Helsinki

Finland

00029 HUS

Sponsor information

Organisation

Department of Gynecology and Obstetrics, Helsinki University Hospital and Helsinki University

Sponsor details

Haartmaninkatu 2 PL 140 Helsinki Finland 00029 HUS

Sponsor type

Hospital/treatment centre

ROR

https://ror.org/02e8hzf44

Funder(s)

Funder type

Not defined

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Study results will be analyzed during summer and fall of 2015. Publication is planned to December 2015 or by the latest January 2016.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available