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Effect of hands-on training for residents on their performance and confidence in performing vacuum extraction assisted delivery

Submission date
24/11/2015

Recruitment status
No longer recruiting

Registration date
19/01/2016

Overall study status
Completed

Last Edited
14/02/2018

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Vaginal birth (delivery of a baby through the vagina without medical assistance) is the natural way for a baby to be born. For some women however, the final stages of labour can be extremely difficult, and so medical assistance is required. Vacuum extraction is a procedure in which a vacuum device is used in order to help to deliver a baby during the final stages of labour. This technique is considered to be a basic skill, and all residents choosing to specialise in obstetrics must learn to perform it in the early stages of their training. In Finland residents and medical students encounter and treat patients at a very early stage. The aim of this study is to look at how hands-on training affects the learning of vacuum extraction procedures and the confidence of the residents.

Who can participate?
All residents working in the maternity ward of a participating hospital that perform vacuum extractions, and their patients (new mothers).

What does the study involve?
For a period of two months, all residents are asked to complete a questionnaire immediately after they perform a vacuum extraction procedure, which is repeated one month after the procedure. This questionnaire is designed to test how well they feel they were able to perform the procedure and their level of anxiety and confidence during the procedure. Two-three days after birth, the patients (new mothers) complete a questionnaire in order to give their opinions on how they feel the procedure went and their feels surrounding the procedure.

What are the possible benefits and risks of participating?
Residents who take part could benefit from the chance to improve their vacuum extraction skills. There are no risks of residents taking part in the study. There are no specific benefits to patients taking part, although the standard risks of vacuum extraction still apply.

Where is the study run from?
Helsinki University Hospital (lead centre) and three other hospitals with maternity wards in Finland.

When is the study starting and how long is it expected to run for?
November 2014 to January 2019

Who is funding the study?
University of Helsinki (Finland)

Who is the main contact?
Dr Sabrina Forsell

Contact information

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
Assesment of hands-on training - effect on resident's performance and confidence in performing vacuum extraction assisted delivery - a prospective single center study

Acronym

VacuEdu

Study objectives
Hands-on training on phantoms for residents can improve performance and confidence in performing vacuum extraction assisted delivery. It can also improve the experience of the mother increasing feelings of security, trust and improve communication between doctor and mother.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee for Gynecology and Obstetrics, Pediatrics and Psychiatry at The Hospital District of Helsinki and Uusimaa, 24/09/2015. Ref nr 301/13/03/03/2015

Study design
Prospective interventional study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Assisted delivery by vacuum extraction

Interventions
All residents participating, form the same study arm. They serve as their own controls, as evaluation is done for every vacuum extraction during one month before the intervention and one month after. The evaluations are done by self assessment, objective assessment by midwife or senior obstetrician and patient.

The residents fill out a questionnaire immediately after every performed vacuum extraction done within 1 month prior and post intervention. The patients fill in a questionnaire at the ward before release, approximately 2-3 days post-partum. At the same time they fill in the written consent for participating in the study.

Intervention Type
Behavioural

Primary outcome measure

1. Performance in vacuum assisted delivery is measured using an OSATS-type structured form for every performed vacuum extraction done within 1 month prior and post intervention
2. Grade of anxiety and confidence experienced by the resident using a structured questionnaire immediately after every performed vacuum extraction within 1 month prior and post intervention
3. Mother's experience of security, trust and communication during the assisted delivery a questionnaire at 2 days after delivery

Secondary outcome measures
1. Vaginal tear rate is determined by reviewing patient notes of tear evaluation done immediately post-partum
2. Condition of the newborn is determined by reviewing patient notes. Evaluation of newborn is done according to general practice 1-10min post partum (Apgar points and umbilical cord blood pH).

Overall study start date
01/11/2014

Completion date
31/05/2019

Eligibility

Key inclusion criteria
Patients:
1. Female
2. All mothers who have had an vacuum extraction delivery performed by a resident, regardless of indication, at the delivery units of Helsinki University Hospital

Residents:
Working in a Department of Gynecology and Obstetrics in a participating hospital.

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
400-800

Key exclusion criteria
Patients:
1. Mothers who's vacuum extraction assisted delivery was performed by a specialist obstetrician or gynecologist
2. Inadequate language skills to fill in the form (in Finnish or Swedish)

Residents:
None

Date of first enrolment
01/01/2016

Date of final enrolment
01/01/2019

Locations

Countries of recruitment
Finland

Study participating centre
Helsinki University Hospital
Department of Obstetrics and Gynecology
Naistenklinikka PL140
Haartmaninkatu 2
Helsinki and Espoo
Finland
00029 HUS

Study participating centre
Meilahti hospital
Haartmansgatan 4
Helsinki
Finland
00290

Study participating centre
Jorvi Hospital
Åbovägen 150
Esbo
Finland
00029

Sponsor information

Organisation
Helsinki University Hospital

Sponsor details
Department of Gynecology and Obstetrics
Naistenklinikka PL140
Haartmaninkatu 2
Helsinki
Finland
00029 HUS

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02e8hzf44

Funder(s)

Funder type
University/education

Funder Name
University of Helsinki

Results and Publications

Publication and dissemination plan
Dissemination of trial results will be done during the winter of 2016-2017, publication approximately in 05/2017

Intention to publish date
01/05/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available