

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 19/01/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 14/02/2018	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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 feelings 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

Contact name

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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

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/02e8hzhf44>

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