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Training in assisted birth: the TAB study

Submission date
23/07/2018

Recruitment status
No longer recruiting

Registration date
07/08/2018

Overall study status
Completed

Last Edited
26/04/2022

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
The BD Odon Device is a new device to help with assisted vaginal birth (AVB). It could potentially reduce the risk of injury to the mother and baby, as its mechanism of action is different to that of forceps and vacuum extraction. Before the device's use in clinical trials the researchers wish to devise and explore the potential benefits of an AVB training programme. Studies of AVB conclude that simulation and training should logically come before clinical experience, allowing for absorption of knowledge and skills in a safe environment. Simulation has been also suggested as an important training technique to increase trainees' confidence. The Royal College of Obstetricians and Gynaecologists (RCOG) guidance on performing AVB has a clear assessment method through the objective structured assessment of training skills (OSATS). This consists of evaluation of generic technical skills and evaluation of key operative steps. The aim of this study is to explore the effect of simulation training with the BD Odon Device.

Who can participate?
Qualified doctors working clinically in obstetrics

What does the study involve?
Participants undertake an AVB training session. This includes an instructional video on the use of the BD Odon Device and intensive 1:1 practical teaching of how to use the BD Odon Device on a high-fidelity pelvic simulator. Training also includes revision and practice in the correct technique for using ventouse and forceps. Staff receive AVB training, including hands-on practical teaching on a high-fidelity pelvic simulator, as part of the current recognised Royal College of Obstetricians and Gynaecologists training course, ROBuST. Clinicians individually arrange a convenient time with the research team to undertake the training and training assessments; this is to fit around their clinical commitments. They participate in one or several visits, depending on availability and convenience.

What are the possible benefits and risks of participating?
Obstetricians have refresher teaching on AVB as well as training on the BD Odon Device, for some a new obstetrical instrument. It will aid their clinical skills and allow them to feel more confident with managing an AVB. Doctors may feel they do not wish to be assessed on a simulated AVB and may feel apprehensive about being compared to their peers. They may be concerned that they will not be able to complete the assessments. They are reassured that this is not in any way a formal assessment and will not be part of their own assessments or appraisal

in any way. The results of this will be completely confidential and only seen by the research team. Participants are not under any obligation to take part in the study and may choose not to participate at any time.

Where is the study run from?
Southmead Hospital (UK)

When is the study starting and how long is it expected to run for?
November 2017 to September 2019

Who is funding the study?
Bill and Melinda Gates Foundation (USA)

Who is the main contact?
Dr Emily Hotton
emily.hotton@nhs.net

Contact information

Type(s)
Public

Contact name
Dr Emily Hotton

ORCID ID
https://orcid.org/0000-0002-8570-9136

Contact details
The Chilterns
Southmead Hospital
Westbury-on-Trym
Bristol
United Kingdom
BS10 5NB
+44 (0)1173232322
emily.hotton@nhs.net

Additional identifiers

Protocol serial number
2.1

Study information

Scientific Title
Practitioner-reported confidence, competence and knowledge following training in assisted vaginal birth: an observational cohort study

Acronym

TAB

Study objectives
This training assessment study aims to explore the effect of simulation training on a novel medical device in obstetrics across several domains.

Ethics approval required
Old ethics approval format

Ethics approval(s)
This is a study that is on doctors working within their clinical capacity on simulation so does not require ethics approval. HRA approval was given 21/06/2018, IRAS number: 249279

Study design
Observational cohort study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Simulation study, focussing on assisted vaginal birth within obstetrics

Interventions
The BD Odon Device is a technological innovation to facilitate the performance of assisted vaginal birth (AVB). The BD Odon Device presents specific features that could potentially reduce the risk of maternal and fetal injury, as its mechanism of action is different to that of forceps and vacuum extraction.

Participants will undertake an assisted vaginal births training session. This will include an instructional video on the use of the BD Odon Device and intensive 1:1 practical teaching of how to use the BD Odon Device on a high-fidelity pelvic simulator. Training will also include revision and practice in the correct technique for using ventouse and forceps. Staff will be exposed to AVB training, including hands-on practical teaching on a high-fidelity pelvic simulator, as part of the current recognised Royal College of Obstetricians and Gynaecologists training course, ROBuST.

Clinicians will individually arrange a convenient time with the research team to undertake the training and training assessments; this is to fit around their clinical commitments. They will participate in one or several visits, depending on availability and convenience.

Intervention Type
Device

Primary outcome(s)
Outcomes are measured at baseline (pre-training) and then again measured post training. This will be any time in the 2 weeks following training, depending on availability and convince of the participant:
1. Training success: ability to perform a delivery scored on a mark scheme for both practical and

verbal recall
2. Change in confidence assessed upon their simulated delivery using a modified version of the six-item, five-point confidence scoring tool previously validated for gynaecology trainees and has already been used and adapted to assess confidence in assisted vaginal birth
3. Change in knowledge: five questions are asked requiring free text responses which have been devised by a multidisciplinary team

Key secondary outcome(s))
Outcomes are measured at baseline (pre-training) and then again measured post training. This will be any time in the 2 weeks following training, depending on availability and convince of the participant:
Expectations and experiences of training, measured using three free text boxes exploring training expectations and five free text boxes exploring experiences of training

Completion date
30/09/2019

Eligibility

Key inclusion criteria
1. Qualified doctor and working clinically in obstetrics
2. Able to provide informed consent

Participant type(s)
Health professional

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Physical disability or injury that would prevent participant from using the investigational device

Date of first enrolment
26/06/2018

Date of final enrolment
30/06/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Southmead Hospital
Research and Innovation, Floor 3, Learning & Research Building
Bristol
United Kingdom
BS10 5NB

Sponsor information

Organisation
North Bristol NHS Trust

ROR
https://ror.org/036x6gt55

Funder(s)

Funder type
Charity

Funder Name
Bill and Melinda Gates Foundation

Alternative Name(s)
Bill & Melinda Gates Foundation, Gates Foundation, Gates Learning Foundation, William H. Gates Foundation, BMGF, B&MGF, GF

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

The data will be held on the University of Bristol server. It will not be made available immediately as some of the data may be used in another study. This is included in the consent form for the TAB study.

IPD sharing plan summary

Not expected to be made available