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The Simulation Training for Operative vaginal Birth – Evaluation (STROBE) study

Submission date
05/03/2018

Recruitment status
No longer recruiting

Registration date
20/04/2018

Overall study status
Completed

Last Edited
23/11/2020

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Operative vaginal birth (OVB) is vaginal delivery of a baby performed with the help of forceps or a vacuum device. OVB is a vitally important tool which can improve outcomes in situations of full cervical dilation and either fetal distress or prolonged labour. OVB, compared to the alternative management (Caesarean section), is associated with lower rates of major maternal haemorrhage (bleeding), reduced analgesia (pain relief) requirements and shorter hospital stay. Babies delivered via OVB also have lower rates of admission to neonatal intensive care units. Currently there is no training course for obstetricians in OVB that has shown benefits in patient-related outcomes. The existing Royal College of Obstetricians and Gynaecologists (RCOG) Operative Birth Simulation Training (ROBUST) course is sporadically undertaken by junior trainees in England. This study involves delivering locally-delivered OVB training in four large maternity units within the South West of England. The innovative package of structured training has been developed by a multi-disciplinary team of obstetricians and midwives, in collaboration with the Royal College of Obstetricians and Gynaecologists (RCOG). The aim of this study is to implement this training course and compare routinely collected patient outcomes before and after training to establish the patient benefit of simulation training for all practitioners in OVB.

Who can participate?
Mothers who have an OVB

What does the study involve?
Trainees in Obstetrics and Gynaecology receive structured simulation training in OVB (the ROBuST course). The intervention is delivered by local faculty of senior obstetricians and midwives. The ROBuST course is a one-day course that uses simulation models to teach the spectrum of OVB manoeuvres – rotational and non-rotational forceps and vacuum deliveries, as well as techniques for complex Caesarean sections. Outcomes for mothers and babies who have had an OVB are collected before and between 3 months and 9 months after the delivery of training in each of the four maternity units.

What are the possible benefits and risks of participating?
This will be the first study to introduce and test a training intervention designed to improve the outcomes of OVB. Should this study demonstrate that locally-delivered training improves

outcomes, the RCOG will include attendance at such a course in the curriculum for all trainee obstetricians within the UK. The benefits of this study could be to mothers and babies, as well as the NHS and wider society through reduction in costs associated with additional care and support. There is minimal risk associated with taking part in this study as it only analyses routinely collected data.

Where is the study run from?
1. Southmead Hospital (lead site) (UK)
2. St Michael's Hospital (UK)
3. Royal United Hospital (UK)
4. Gloucestershire Royal Hospital (UK)

When is the study starting and how long is it expected to run for?
November 2017 to August 2018

Who is funding the study?
The Health Foundation (UK)

Who is the main contact?
Laura Timlin
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Contact information

Type(s)
Scientific

Contact name
Ms Laura Timlin

Contact details
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Additional identifiers

Protocol serial number
34506

Study information

Scientific Title
The Simulation Training for Operative vaginal Birth – Evaluation (STROBE) study

Acronym
STROBE

Study objectives
Currently there is no training course for obstetricians in operative vaginal birth (OVB) that has shown benefits in patient-related outcomes. The existing Royal College of Obstetricians and Gynaecologists (RCOG) Operative Birth Simulation Training (ROBUST) course is sporadically undertaken by junior trainees in England. This project seeks to implement this training course and compare routinely collected patient outcomes before and after training to establish the patient benefit of simulation training for all practitioners in operative vaginal birth.

Ethics approval required
Old ethics approval format

Ethics approval(s)
STROBE is exempt from REC review. HRA approval received 22/11/2017, IRAS 223629

Study design
Non-randomised; Both; Design type: Process of Care, Management of Care, Cohort study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Reproductive health and childbirth, Primary sub-specialty: General Obstetrics/ Midwifery; UKCRC code/ Disease: Reproductive Health and Childbirth/ Delivery

Interventions
The intervention studied will be the local provision of structured simulation training in operative vaginal birth (the ROBuST course) to trainees in Obstetrics and Gynaecology. The intervention will be delivered by local faculty of senior obstetricians and midwives. The ROBuST course is a one-day course that utilises simulation models to teach the spectrum of operative birth manoeuvres – rotational and non-rotational forceps and vacuum deliveries, as well as techniques for complex Caesarean sections. Follow-up of clinical outcomes will be between 3 months and 9 months after the provision of training, depending on site.

Intervention Type
Other

Primary outcome(s)
Failure to achieve vaginal birth with the primary chosen instrument; Timepoint(s): 01/06/2018

Key secondary outcome(s))
1. Use of second instrument to achieve operative vaginal birth (forceps or ventouse)
2. Caesarean section
3. Episiotomy
4. Perineal trauma (1st/2nd/3rd/4th degree tear)

5. Cervical tear requiring suturing
6. General anaesthesia
7. Estimated blood loss (ml)
8. Apgar score at 1, 5 and 10 minutes
9. Umbilical artery pH
10. Shoulder dystocia (Yes/No)
11. Admission to Neonatal Intensive Care Unit (for any reason immediately following birth)
12. Neonatal death within 28 days of birth (for any reason)

All outcome measures are routinely assessed and recorded contemporaneously by the obstetrician performing the attempted operative vaginal birth

Completion date
31/08/2018

Eligibility

Key inclusion criteria
1. The woman had a birth conducted within a study site during the applicable study time period, by any doctor, trained or untrained
2. An operative vaginal birth instrument (forceps or vacuum) was applied to a fetal head
3. The woman had a singleton pregnancy

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
Excludes an instrumented Caesarean birth

Date of first enrolment
13/02/2018

Date of final enrolment
01/06/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Southmead Hospital (lead site)
North Bristol NHS Trust
Southmead Road
Bristol
United Kingdom
BS10 5NB

Study participating centre
St. Michael's Hospital
University Hospitals Bristol NHS Foundation Trust
Southwell Street
Bristol
United Kingdom
BS2 8EG

Study participating centre
Royal United Hospital
Royal United Hospitals Bath NHS Foundation Trust
Combe Park
Bath
United Kingdom
BA1 3NG

Study participating centre
Gloucestershire Royal Hospital
Gloucestershire Hospitals NHS Foundation Trust
Great Western Road
Gloucester
United Kingdom
GL1 3NN

Sponsor information

Organisation
North Bristol NHS Trust

ROR
https://ror.org/036x6gt55

Funder(s)

Funder type
Charity

Funder Name
The Health Foundation; Grant Codes: AIMS 69396

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository. A consolidated anonymised raw master dataset generated during the current study will be uploaded to a publicly available repository hosted by the University of Bristol at the end of data analysis (University of Bristol Research Data Repository, www.data.bris.ac.uk). Data will be publicly available for any form of analysis for 20 years after the end of the study. The DOI of this specific data repository will be included in the final results publication.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	02/04/2019	23/11/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version v7		02/04/2019	No	No