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The BD Odon Device for assisted vaginal birth

Submission date
23/07/2018

Recruitment status
No longer recruiting

Registration date
27/07/2018

Overall study status
Completed

Last Edited
18/08/2023

Condition category
Pregnancy and Childbirth

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[X] Individual participant data

Plain English summary of protocol

Background and study aims
Around one in eight women in the UK require assistance to give birth to their baby vaginally. Currently, doctors use either forceps or a ventouse (a suction cup) to help women have their babies in this manner. This is known as an assisted vaginal birth (AVB). Most mothers and babies do very well after an AVB, and the procedure is usually much better for both mothers and babies than the alternative, an emergency Caesarean section. However, women and their babies can sometimes be harmed by an AVB. Mothers have a greater tendency to have severe tears of the vagina and sometimes the rectum (back passage) compared to a spontaneous vaginal birth. Mothers may have more pain while healing (usually for one to two weeks) following a birth that has been assisted by forceps or ventouse. Babies may develop bruising over the scalp or face where the forceps or ventouse have been applied. Babies can also very rarely (around 1 in 1000) sustain more serious harm, such as nerve injuries or bleeding into the brain or eye. Therefore, although AVB is generally very safe and usually better than the alternative (an emergency caesarean section), it is sensible to try to improve the technique to assist a vaginal birth and reduce the risks to both mothers and their babies. Unfortunately, no new types of devices to assist vaginal birth have been introduced into practice since the ventouse in the 1950s.The BD Odon Device is a new device for AVB that has been designed by a team of midwives, doctors and engineers. The BD Odon Device works by placing a cuff of air which is attached to a sleeve, around the baby's head. The doctor then gently pulls on this sleeve and air cuff to assist the birth of the baby. In this study, the BD Odon Device is used to help women give birth in cases where it is necessary to assist the birth of the baby. The aim of this study is to evaluate the safety and effectiveness of the BD Odon device and seek the views of women and healthcare professionals on its use. The information gained from the study will be used to plan a large study that will directly compare the BD Odon Device with the ventouse.

Who can participate?
Pregnant women aged 18 and over in the final stage of labour (full cervical dilatation) who require an AVB. This could be because their labour has slowed down, there are concerns about their baby's heart rate, or there is a medical reason to shorten the amount of time a woman should push for during labour

What does the study involve?
Participants have their baby's birth assisted with BD Odon Device. Some participants take part in an audio-recorded interview exploring their satisfaction of the birth of their baby. Apart from

these research procedures, participants receive usual care from all staff before, during and after childbirth from the staff of North Bristol NHS Trust.

What are the possible benefits and risks of participating?
There may be no direct benefit; the researchers believe that the new device is safe but it is not known whether it is better than the ventouse or forceps, or even what 'better' means. So, the main benefit will be helping with the next stage of the research and possibly helping women who might need an assisted vaginal birth in the future. It is possible that the new device will be better than ventouse or forceps. Participants will receive additional telephone follow-up from the study midwives and doctors following the birth. Many women who have participated in other maternity research studies conducted at NBT have commented how much they value the opportunity to speak to a midwife over the telephone in the weeks after their baby's birth. If the BD Odon Device is found to be easier to use, is as safe, or safer, than the current alternatives, and is acceptable to both women and birth practitioners, then the use of the device could play a major role in improving maternity care for mothers and their babies both in the UK and across the world. At present, there are many women in low income countries who do not have access to an assisted vaginal birth even if it would be life-saving. The BD Odon Device has the potential to address this unmet need. The BD Odon Device may not be as effective as the current options for assisted vaginal birth and the birth may therefore need to be further assisted with forceps or ventouse. As the BD Odon Device has only been used in a small number of women the safety profile of the device is not yet completely understood. There is a risk that women or their babies may develop complications as a result of the use of the device (e.g., vaginal tears, post-partum haemorrhage, bruising). It is expected these complications will be similar to those risks associated with the use of forceps and ventouse.

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

When is the study starting and how long is it expected to run for?
March 2018 to August 2019

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

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
38989

Study information

Scientific Title
The BD Odon Device for assisted vaginal birth: a safety and feasibility study

Acronym
ASSIST

Study objectives
The ASSIST Study is a feasibility study of the BD Odon Device for women having an assisted vaginal birth (AVB). The ASSIST Study will determine to what extent the BD Odon Device is safe and effective for women and babies who require an AVB.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Central – Berkshire, provisional favourable opinion 28/06/2018, ref: 18/SC/0344

Study design
Non-randomised; Both; Design type: Treatment, Device, Qualitative

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Assisted vaginal birth

Interventions
Chosen methodology and participant journey
The chosen methodology is an open, non-blinded single-arm single-centre feasibility study. Only one intervention arm has been included – an assisted vaginal birth using the BD Odon Device. A comparative study of the BD Odon Device versus current standard care (Kiwi ventouse) will be required if the BD Odon device is going to be introduced to routine clinical practice, a comparison arm is not required at this point. Numerous previously published studies (including studies carried out at North Bristol NHS Trust) and meta-analyses have already characterised rates of successful birth and adverse outcomes associated with the Kiwi ventouse (success rate = 29.5% in most recent Cochrane review) studies.
Within the study participants (women who require an assisted vaginal birth for a known clinical indication) will have their baby's birth assisted with BD Odon Device (rather than forceps or ventouse – which would be used if they were not participating in the study). Participants will complete, or provide, the following tasks specifically for the research study phase:
• Read the participant information leaflet (PIL) about the study phase
• Provide written consent to participate by signing the consent form
• Complete a quality of life utility (EQ-5D) prior to birth
• Undergo an assisted vaginal birth using the BD Odon Device, which may be observed
• Complete or provide a Patient Perception Score (PPS), maternal pain, method of feeding and quality of life utility (EQ-5D-5L) on day 1 postnatal in person, by telephone or post
• Complete or provide maternal reported pain and method of feeding on day 7 postnatal (either by post or via telephone)
• Complete or provide quality of life utility (EQ-5D-5L), maternal reported pain, method of feeding and Healthcare Utilisation Form (HUF) day 28 postnatal (either by post or via telephone)
• Complete maternity continence function questionnaire and method of feeding at 90 days postnatal (either by post or via telephone)
• Some participants take part in an audio-recorded interview exploring their satisfaction of the birth of their baby.
Outwith these research procedures, participants will receive usual care from all staff before, during and after childbirth from the staff of North Bristol NHS Trust.

Participants will be asked to provide maternal-reported outcomes at four time-points after the birth of their baby. The schedule, setting and duration of these interviews are listed below:
Day 1. Face-to-face interview, in hospital (or over phone if discharged), approximately 20 minutes
Day 7. Telephone interview, approximately 10 minutes
Day 28. Telephone interview, approximately 20 minutes
Day 90. Telephone interview, approximately 20 minutes
Furthermore, participants will also be invited to take part in open-ended qualitative interviews about their experience of being a study participant and having an AVB with the BD Odon Device. These interviews will take place within 90 days of birth and will take place in a location of the participants preference (this can include their own home). Although non-prescriptive in nature

these interviews are not anticipated to last more than one hour in duration. A minimum of ten women will be invited to interview, and no more than 30 will be interviewed.

Required sample size
Forty women with data for the primary outcome will be required for a complete sample. A complete sample size of 40 women will enable the estimation of the rate of successful assisted vaginal birth of 80% (assumed) to within a 95% confidence interval of +/- 12%. The sample size will also demonstrate AVB requiring use of a secondary instrument of 50% to within a 95% confidence interval of +/- 15%. The sample size will also be sufficient to make preliminary estimates of rates of rarer but significant outcomes such as obstetric anal sphincter injury and neonatal injury.

Research timetable
The ASSIST study will commence in August 2018 and will continue for eight months (or until 40 participants have had an AVB within the study). After every five included births the Trial management Group (TMG) and Sponsor will meet and formally review all outcomes from a safety perspective within the study. No formal interim analyses of clinical outcomes will take place. Following the final birth within the study, an independent Data Monitoring Committee (DMC) will review all outcomes and issue a formal report to the Trial Steering Committee (TSC) and Sponsor. This will take place no more than three months after completion of follow-up for the final included birth (projected to be May 2019). The TSC will make a determination if the research team should apply to REC for progression to a randomised controlled trial.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Not provided at time of registration

Primary outcome measure
Successful vaginal birth with BD Odon Device; Timepoint(s): At birth

Secondary outcome measures
Maternal outcomes:
1. Failure to achieve a vaginal birth with the assistance of a BD Odon Device, measured at birth
2. Use of emergency Caesarean section to achieve birth, measured at birth
3. Postpartum haemorrhage >3,000ml, measured within 24 hours of birth
4. 3rd or 4th degree anal sphincter tear, measured at birth
5. Cervical tear, measured at birth
6. Maternal death up to 90 days post birth
7. Maternal health-related quality of life (EQ-5D-5L) antenatally, at day one and day 28 postnatal
8. Maternal pain: use of analgesia measured at day 1 and day 7 postnatal, maternal reported pain measured on 11-point Likert scale at day 1, day 7, day 28 and day 90 postpartum
9. Maternal continence, measured with the Aberdeen Postnatal Incontinence Questionnaire at 90 days postpartum
10. Maternal satisfaction with birth experience, measured with the Patient Perception Score on day 1 postnatal

Neonatal outcome measures:
1. Apgar score <7 at 5 minutes
2. Neonatal pain, measured by Neonatal Infant Pain Score at 2 and 6 hours after birth
3. Shoulder dystocia, measured at birth
4. Admission to Neonatal Intensive Care Unit within 28 days after birth
5. Phototherapy for bruising, measured within 7 days of birth
6. Pressure necrosis of fat or skin, measured within 28 days of birth
7. Other neonatal injury within 28 days of birth
8. Neonatal death within 28 days of birth
9. Failure to establish normal feeding pattern (defined as ≤1 feed at 10 hours of age)
10. Method of feeding on day 1, day 7, day 28 and day 90 postpartum

1. Failure of a component of the BD Odon Device before or during delivery
2. Practitioner reported perception of BD Odon Device (willingness to use device, overall ease of use, ease of device setup, ease of application, ease of withdrawal, comfort, ease of deflation – all measured on five-point Likert scale) measured within 24 hours of birth
3. Patient recruitment, participation and follow-up rates and reasons for declining or withdrawal (medical, personal, logistic, other)

Overall study start date
06/03/2018

Completion date
01/08/2019

Eligibility

Key inclusion criteria
Women will be eligible to participate in the study if ALL of the following apply:
1. The woman is ≥18 years of age
2. The woman has a singleton pregnancy
3. The pregnancy is ≥36+0 weeks' gestation
4. The woman may require an AVB for a clinical indication – see below

Fetal
Presumed fetal compromise

Maternal
1. Maternal fatigue/exhaustion
2. Lack of continuing progress of the fetal head following the time limits of active second stage recommended by the National Institute of Health and Care Excellence (NICE) (2 hours for a woman in her first pregnancy with no analgesia, 1 hour for a woman in her first pregnancy with analgesia who has already been in the second stage of labour for 2 hours, 1 hour for women in a 2nd or greater pregnancy)
3. To shorten and reduce the effects of the second stage of labour on medical conditions (i.e. cardiac disease, myasthenia gravis, hypertensive crises, proliferative retinopathy, spinal cord injury patients at risk of autonomic dysreflexia, etc)
*Adapted from the Royal College of Obstetricians & Gynaecologists 2011
4. The woman has effective analgesia in place during the use of the instrument (i.e. epidural,

spinal or pudendal block, or perineal infiltration with local anaesthetic)
5. The practitioner providing the woman's care in labour determines that she requires an AVB, and there is no obstetric indication for an alternative method of AVB (forceps or ventouse)

Babies will be included if their mother is participating in the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
Planned Sample Size: 48; UK Sample Size: 48

Total final enrolment
97

Key exclusion criteria
Women may not enter the study, or will be removed from the study, if any of the following apply:
1. The woman does not fulfil all of the inclusion criteria listed
2. There is a diagnosis of a fetal skull abnormality precluding AVB (i.e. macrocephaly)
3. There is a known osteogenesis imperfecta affected pregnancy
4. There is suspicion of a fetal bleeding disorder (von Willebrand's disease, AITP, haemophilia etc)
5. Intrauterine fetal death in the current pregnancy
6. The woman is currently serving a prison sentence
7. The woman lacks capacity to consent
8. The woman has a lack of ability to read or understand English as this would preclude successful completion of questionnaires
9. Latex sensitivity
10. Fetal bradycardia

Date of first enrolment
16/08/2018

Date of final enrolment
01/05/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Southmead Hospital
North Bristol NHS Trust
Southmead Road
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Sponsor information

Organisation
North Bristol NHS Trust

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/036x6gt55

Funder(s)

Funder type
Charity

Funder Name
Bill and Melinda Gates Foundation; Grant Codes: OPP1184825

Alternative Name(s)
Bill & Melinda Gates Foundation, 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

Publication and dissemination plan
The protocol and final results of this study will be published in a high-impact peer reviewed journal. The protocol will be published prior to the end of data collection and the final results will be published no later than one year after the end of data collection.

Intention to publish date
01/08/2020

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	05/03/2019	26/10/2020	Yes	No
Results article		13/12/2020	27/07/2021	Yes	No
Results article	qualitative study of participant experiences	15/12/2021	17/12/2021	Yes	No
Results article	integrated qualitative case study methodology	04/08/2022	05/08/2022	Yes	No
HRA research summary			28/06/2023	No	No
Dataset	Copies of the case report forms for the ASSIST Study		18/08/2023	No	No