ISRCTN38829082 https://doi.org/10.1186/ISRCTN38829082

The BD Odon Device™ for assisted vaginal birth

Submission date
26/06/2019

Recruitment status
No longer recruiting

Registration date
26/06/2019

Overall study status
Completed

Last Edited
23/02/2024

Condition category
Pregnancy and Childbirth

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims

Around one in eight women in the U.K. who give birth to their baby vaginally, will require assistance, and currently, doctors will use either forceps or a ventouse (a suction cup) to help assist the birth. 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. Some 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 following a birth that has been assisted by forceps or ventouse (usually for one to two weeks). Babies may develop bruising over their 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 important that we continue to find ways to try to improve the technique to assist a vaginal birth and reduce the risks of harm 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.

A clinical study using the BD Odon Device, called the ASSIST Study, was conducted at a single maternity unit, North Bristol NHS Trust, in the UK. Forty women who required an assisted vaginal birth for a clinical indication had an attempted birth using the BD Odon Device. Formal analysis of all of the cases in the study is on-going, and hence we can only provide provisional results at this stage. The results showed that of the 40 cases in which an Odon assisted birth was attempted, there has been no harm to mothers or babies related to using the device which demonstrates early indication of device safety.

19 (48%) births were successfully completed with the BD Odon device. The reasons for the lower than expected success rate needs to be explored, specifically focussing on: learning curve and technique of the doctors using this new device; and potential modifications to device design. It is therefore reasonable at this stage, to conduct a follow-on clinical study to further investigate the safety and efficacy of the BD Odon Device in its indicated use. The inclusion criteria for the ASSIST II Study has been changed, ensuring that babies delivered with the BD Odon Device have

their vertex at 1cm below the ischial spines or below.
Considered together, data from the studies of the BD Odon Device to date suggest that the BD Odon Device does not present a higher risk to mothers or babies compared to current standard care (forceps and ventouse).

In this study, we will continue to use the BD Odon Device to help women give birth in cases where it is necessary to assist the birth of the baby and we will further evaluate the safety and effectiveness of the BD Odon device.

Who can participate?
Pregnant women over the age of 18 who require AVB

What does the study involve?
Participants will undergo AVB using the BD Odon Device™. They will also be required to complete a number of questionnaires at clinic visits before and after giving birth.

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. A previous study, the ASSIST Study has demonstrated that current evidence suggests there is no increased risk to women or babies from the BD Odon Device.
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?
August 2019 to December 2021 (updated 10/03/2022, previously: September 2021; updated 12 /10/2021, previously: October 2021; updated 10/03/2021, previously: November 2020)

Who is funding the study?
The Bill and Melinda Gates Foundation

Who is the main contact?
Dr Emily Hotton, emily.hotton@nbt.nhs.uk
Dr Joanna Crofts, Joanna.Crofts@nbt.nhs.uk
Ms Abi Loose, Abi.Loose@nbt.nhs.uk (added 10/03/2021)

Study website
https://www.nbt.nhs.uk/ASSISTII

Contact information

Type(s)
Scientific

Contact name
Dr Emily Hotton

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

Contact details
The ASSIST II Research Office
The Chilterns
Southmead Hospital
Bristol
United Kingdom
BS10 5NB
0117 414 6764
assist@nbt.nhs.uk

Type(s)
Scientific

Contact name
Dr Joanna Crofts

Contact details
The Chilterns
Southmead Hospital
Westbury-on-Trym
Bristol
United Kingdom
BS10 5NB
+44 0117 4146764
Joanna.Crofts@nbt.nhs.uk

Additional identifiers

EudraCT/CTIS number
2019-001674-28

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
0.2

Study information

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

Acronym
ASSIST II

Study objectives
The ASSIST II Study is a feasibility study of the BD Odon Device for women having an assisted vaginal birth (AVB). The ASSIST II Study will determine to what extent the BD Odon Device is safe and effective. It is intended to also define the clinical circumstances in which the device is most effective and in addition studying the learning curve of the operator and the most effective user technique.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/06/2019, NHS HRA REC South Central – Berkshire (Easthampstead Baptist Church, South Hill Road, Bracknell, RG12 7NS; 02071048046; nrescommittee.southcentral-berkshire@nhs.net), ref: 19/SC/0226.

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
https://www.nbt.nhs.uk/ASSISTII

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

Interventions
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 or if an Odon trained operator was not available). Participants will complete, or provide, the following tasks specifically for the research study phase:
• Read the participant information leaflet (PIL) about the study and watch the ASSIST II Study consenting video
• 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
• 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 a Patient Perception Score (PPS), maternal pain, method of feeding on day 7 postnatal (either by post or via telephone)
• Complete or provide a Patient Perception Score (PPS), maternal pain, method of feeding, provide quality of life utility (EQ-5D-5L) 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 views on the consenting process
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 the consenting process. 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
One hundred and four women with data for the primary outcome will be required for a complete sample. Assuming that the success rate (P) of a poor AVB is 50%, and the success rate of a good AVB would be 65% or more, and one-sided alpha risk of 5% and power of 90%, a study with 104 participants will be required to decide whether the success rate of the BD Odon Device is less than or equal to 50%, or greater than or equal to 65%.
A study requires 104 subjects to decide whether the proportion responding, P, is less than or equal to 0.500 or greater than or equal to 0.650.

Research timetable
The ASSIST II study will commence in August 2019 and will continue for ten months (or until 104 participants have had an AVB within the study). Every month 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 but an independent Data Monitoring Committee will perform a safety review after the 42nd attempted birth. 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 September 2020). 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
Phase II

Drug/device/biological/vaccine name(s)
The BD Odon Device™

Primary outcome measure
Primary endpoint: Rate of births successfully assisted with the BD Odon Device
A birth will be defined as 'successful' if all of the following criteria are met:
1. The birth of the baby is expedited with the Odon Device
2. There are no serious maternal adverse reactions related to the use of the device during birth
3. There are no serious neonatal adverse reactions related to the use of the device during birth

Secondary outcome measures
Secondary outcome measures are categorised below and include measures needed to test the feasibility of a RCT:
1. Birth
1.1 Time from "decision to perform assisted birth" to "birth" (minutes)
1.2 Time from "device application" to "birth" (minutes)
1.3 Time between "decision to perform assisted birth" to "time of Odon application"
1.4 Location of birth
1.5 Mode of birth following failed use of Odon device
2. Device
2.1 Failure of a component of the Odon device
2.2 Number of applications of device
2.3 Number of pulls of the device
2.4 Any trauma caused by first device application
2.5 Perceived reason for device failure from operator (maternal/clinical/device/other)
3. Maternal
3.1 Weighed estimated blood loss
3.2 Perineal and anal sphincter injury (1st/2nd/3rd/4th degree tears and episiotomy)
3.3 Ischio-rectal fossa defect
3.4 Cervical tear (present not requiring suturing)
3.5 Cervical tear (present requiring suturing)
3.6 Labial tear requiring suturing

3.7 Lower segment Caesarean section performed (Yes/No)
3.8 Use of analgesia days 1, 7 and 28 post natal
3.9 Details of analgesia used at days 1, 7 and 28 post natal
3.10 Maternal death
3.11 Length of hospital stay following birth
4. Neonatal
4.1 Umbilical artery pH and base excess
4.2 Umbilical vein pH and base excess
4.3 Shoulder dystocia
4.4 Apgar scores at 1, 5 and 10 minutes post natal
4.5 Neonatal Infant Pain Scores at 2 and 6 hours post natal
4.6 Neonatal feed by 10 hours post natal
4.7 Method of feeding days 1, 7, 28 and 90 post natal
4.8 Admission to Neonatal Intensive Care Unit (NICU)
4.9 Time spent in NICU (hours)
4.10 Neonatal soft tissue trauma (bruise/scalp/facial injury/cephalohaematoma)
4.11 Neonatal vascular injury (subaponeurotic haemorrhage)
4.12 Neonatal body maps (head and neck)
4.13 Neonatal skeletal injury (bone fracture)
4.14 Neonatal intra-cranial injury (cerebral contusion)
4.15 Neonatal neurological injury still present at day 28 post natal
4.16 Neonatal seizure by day 28 post natal
4.17 Phototherapy for jaundice contributed to by bruising by day 28 post natal
4.18 Anaemia requiring transfusion by day 28 post natal
4.19 Neonatal encephalopathy requiring therapeutic hypothermia within 28 days post natal
4.20 Organ failure within 28 days post natal
4.21 Other neonatal injury
4.22 Neonatal death within 28 days post natal
5. Patient reported outcomes
5.1 Maternal health-related quality of life data (EQ-5D-5L) will be collected during the antenatal period and at day 1 and day 28 post natal.
5.2 Patient perception score of birth experience day 1, 7 and 28 post natal (score out of 15 where 3 is the lowest score possible)
5.3 Maternal perception of pain (11-point Likert scale) at days 1, 7 and 28 post natal
5.4 Maternal continence at day 90 post natal
5.5 Acceptability of partaking in the ASSIST II Study
6. Practitioner secondary reported outcomes
-Practitioner perceived outcomes will be collected for each attempted AVB. The following will be collected on a 5-point Likert scale
6.1 Instrument of choice if BD Odon Device was not used (rotational forceps/non-rotational forceps/KIWI ventouse/silastic ventouse)
6.2 Perceived overall ease of use of device (for all AVBs)
6.3 Ease of device set-up (for all AVBs)
6.4 Ease of device application to the baby's head (for all AVBs)
6.5 Ease of withdrawal of the applicator after application (for Odon births only)
6.6 Comfort with the level of force required to assist the birth of the baby (for all AVBs)
6.7 Ease of deflation of the cuff prior to crowning (for Odon births only)
6.8 Ease of removal of the forceps or ventouse
6.9 In order to further understand the technique for device use, any birth with the BD Odon Device, the practitioner (and research midwife if present) will document the angle of device application using a grid stating whether the handle of the device is pointing: up, down or horizontally. Practitioner acceptability will also be examined.

7. Health Utilisation Form outcomes
-Data regarding visits to a health care professional in either the hospital or community setting within the first 28 days postnatal will be collected.
8. Feasibility of the planned future RCT
8.1 Participant recruitment, participation and follow-up rates and reasons for declining or withdrawal (medical, personal, logistic, other)
8.2 Suitability of outcome measures and overall data collection processes, including complete list of data collection and recruitment rate to the study.
8.3 Ability to collected data from a 'nested' cohort will help demonstrate whether collecting data on a control group in a RCT is feasible

Overall study start date
01/03/2019

Completion date
09/12/2021

Eligibility

Key inclusion criteria
1. Pregnant women aged 18 and over
2. 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
3. Informed consent has previously been given and has been reconfirmed. All 'consent' inclusion have been re-assessed and remain valid.
4. Pregnancy is ≥36+0 weeks' gestation.
5. The woman is in labour and requires an assisted vaginal birth for a clinical indication (as per the Royal College of Obstetricians & Gynaecologists Greentop Guideline, 2011). The RCOG specific requirements for AVB are fulfilled (as per the Royal College of Obstetricians & Gynaecologists Greentop Guideline, 2011). The vertex is 1cm or more below ischial spines.
6. 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).
7. 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 metal cup). Availability of a suitably trained practitioner.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants

104

Total final enrolment
126

Key exclusion criteria
Current exclusion criteria as of 10/03/2021:

1. The woman does not fulfil all of the inclusion criteria listed
2. Maternal-reported fetal skull abnormality, fetal osteogenesis imperfecta or fetal bleeding disorder
3. Intrauterine fetal death in the current pregnancy
4. The woman is currently serving a prison sentence
5. The woman lacks the capacity to consent
6. The woman has a lack of ability to read or understand English
7. Sensitivity to latex
8. Informed consent is withdrawn
9. There is an ongoing fetal bradycardia
10. Current confirmed or clinically suspected Covid-19 infection
11. Woman is shielding from Covid-19 due to a medical condition or medication as per current PHE guidance
12. No Odon trained practitioner available to assist the birth

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Previous exclusion criteria:

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. The indication for AVB is a fetal bradycardia which is present and on-going and has not recovered
11. Informed consent is withdrawn at anytime
12. Any of the 'consent' or 'participation' inclusion criteria are not met
13. No Odon trained practitioner available to assist the birth

Date of first enrolment
09/08/2019

Date of final enrolment
07/07/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Southmead Hospital
Southmead Road
Bristol
United Kingdom
BS10 5NB

Sponsor information

Organisation
North Bristol NHS Trust

Sponsor details
Research & Innovation Department
Learning & Research Building
Floor 3
Southmead Hospital
Bristol
Westbury-on-Trym
Bristol
England
United Kingdom
BS10 5NB
+44 (0)117 4149330
researchsponsor@nbt.nhs.uk

Sponsor type
Hospital/treatment centre

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, 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.
(added 09/06/2023): The Protocol has been published (pilot & Feasibility Studies) and the results paper has been accepted for publication (AJOG) and is under the editorial process.

Intention to publish date
09/08/2023

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		19/03/2021	22/03/2021	Yes	No
Other publications	qualitative research undertaken as part of the ASSIST II Trial	15/06/2023	16/06/2023	Yes	No
HRA research summary			28/06/2023	No	No
Results article		30/07/2023	23/02/2024	Yes	No