

# The ASSIST Study - The BD Odon Device for assisted vaginal birth: a safety and feasibility study

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## Method Article

**Keywords:** BD Odon Device, forceps, ventouse, assisted birth, birth, intrapartum research

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# Abstract

**Background:** Assisted vaginal birth is a vital health intervention that can result in better outcomes for mothers and their babies when complications arise in the second stage of labour. Unfortunately, instruments for assisted vaginal birth (forceps and ventouse) are often not utilised in settings where there is most clinical need, resulting in maternal and neonatal morbidity and mortality which could have been prevented. The BD Odon Device is a new device for assisted vaginal birth which may be able to address this unmet need. However, before dissemination the device requires evaluation in robust clinical trials. A feasibility study to investigate the clinical impact, safety and acceptability of the BD Odon Device for assisted vaginal birth is therefore planned. This will provide further information on acceptability, recruitment and the outcome data required to design a future randomised controlled trial of the BD Odon Device versus Kiwi ventouse.

**Methods:** Forty women who require an assisted vaginal birth for a recognised clinical indication will have the birth assisted with the BD Odon Device. The primary outcome is successful vaginal birth completed with the BD Odon Device. Secondary clinical outcomes include maternal and neonatal outcomes, and maternal and practitioner satisfaction. Safety data will be reviewed following every birth.

**Discussion:** A future randomised controlled trial (RCT) of the BD Odon Device versus current standard instrument (the Kiwi ventouse) is planned. The findings of the ASSIST Study will inform the RCT design.

**Trial registration:** ISRCTN registration: ISRCTN10203171 (prospectively registered 27/07/2018).

**Keywords:** BD Odon Device, forceps, ventouse, assisted birth, birth, intrapartum research

## Background

Complications of the second stage of labour (fetal compromise, obstructed labour, maternal exhaustion or maternal medical conditions exacerbated by the act of pushing) remain a major cause of maternal and neonatal mortality and morbidity across the world. Such complications are responsible for 4 to 13% of maternal deaths in Africa, Asia, Latin America and the Caribbean(1), and in 2013 obstructed labour alone accounted for four deaths per million women worldwide(2). This burden of adverse outcomes may be reduced by an appropriately timed and safely performed assisted vaginal birth (AVB). An AVB is performed with either obstetric forceps or ventouse, and reduces adverse outcomes for women and their babies relative to caesarean section performed in the second stage of labour(3). However, AVB rates are minimal in low and middle-income countries (LMICs) where it is likely that there is the greatest need for AVB (Figure 1).

In addition to widespread low levels of utilisation, earlier surveys report significant regions where AVB was not used at all – in 2006 this was the case in 74% of Latin American and Caribbean countries, as well as 30% of countries in sub-Saharan Africa and 40% of countries in Asia (8). In addition to a lack of

trained accouchers in LMICs (9-11), the maintenance and sterilisation requirements of both forceps and ventouse may limit their utilisation (8). There is a significant unmet need for AVB in all maternity settings, but particularly in LMICs.

Forceps are less likely to fail in achieving an AVB when compared to a ventouse however, they are associated with increased maternal perineal and vaginal trauma. The ventouse is less likely to achieve a vaginal birth and its use is associated with an increased risk of neonatal cephalohaematoma and retinal haemorrhage (12). Both devices are efficient but do have caveats for their use. It is possible that a new device may be able to address some of the adverse events associated with the current devices used to assist birth.

The BD Odon Device is a new device for AVB (Figure 2). The use of an air chamber to act as the traction point on the fetal head (rather than the thin metal blades of the forceps) is hypothesized to reduce adverse events associated with the greater pressures applied to the fetal head during the use of forceps. The lack of negative pressure on the fetal head, the mechanism of action of the ventouse, obviates the risk of haematoma and haemorrhage associated with ventouse. Both of these contentions have been supported in pre-clinical simulation studies(13,14). A first in human pilot study of an earlier version of the device in healthy volunteers has been completed demonstrating that assisting birth using the device is feasible(15). Following the completion of extensive simulation studies which included human factors engineering validation testing, it has been deemed appropriate to evaluate the BD Odon Device in the intended target user population(16). To date, the effectiveness and safety of the Odon device compared to other devices remain untested. It is now time to evaluate the clinical effectiveness and safety of the BD Odon Device in its intended clinical setting, using an appropriately powered and robust randomized controlled trial. To inform the design of this study we plan to conduct a safety and feasibility study exploring the clinical impact that the BD Odon device may have on current clinical practice, as well as the safety and acceptability of the device to women, midwives, obstetricians and neonatologists.

## **Methods**

### *Aim*

This feasibility study will investigate the clinical impact, safety and acceptability of the BD Odon Device and assess the feasibility of recruiting women and data collection. It will provide vital information on acceptability, recruitment and the outcome data required to design a future randomised controlled trial of the BD Odon Device versus Kiwi ventouse.

### *Study design*

The ASSIST Study (Assisted Vaginal Birth Study) is a non-randomised feasibility study of 40 women who require an assisted vaginal birth for a recognised clinical indication and who will all have their birth assisted with the BD Odon Device. A CONSORT diagram of the feasibility study is shown in Figure 3.

The ASSIST feasibility study will utilise only one of the devices intended for use in the eventual randomised controlled study (BD Odon Device). This is to establish the safety, acceptability and efficacy of the BD Odon Device prior to moving to a full RCT. The intended comparator (the Kiwi ventouse) will not be evaluated in this study as published evidence on its acceptability and success rate at the intended primary site already exists(17).

### *Population/sample*

Participants will be pregnant women aiming for a vaginal birth who plan to give birth at North Bristol NHS Trust (NBT), Bristol, UK. Recruitment is projected to continue for eight months (due to the AVB rate within the department) after which time it is estimated that 40 sets of primary outcome data will have been recorded.

Prospective participants will receive information on the study in early pregnancy (12 to 28 weeks) via the NBT Maternity 'App' (this 'App' is provided to all pregnant women at NBT and provides information on all aspects of their maternity care) and paper information leaflets, given to women at any hospital admission. Members of the study team will then approach women after 28 completed weeks of pregnancy during antenatal appointments or antenatal admissions, to discuss the study and offer women the opportunity to watch to a video explaining the study. Women who are willing to take part (should they require an AVB) will then be invited to provide informed written consent. Figure 4 below demonstrates the schedule of enrolment, interventions and assessments.

When a woman who has previously consented to participate in the study arrives on the labour ward, her eligibility to participate in the study will be rechecked by a midwife and obstetrician who has been trained in Good Clinical Practice (GCP), and verbal re-confirmation of her consent to take part in the study will be sought by a GCP trained midwife or obstetrician. Case forms can be found in the Additional file A.

### *Inclusion and exclusion criteria*

Women will be able to participate in the ASSIST Study if all of the following apply at initial consent: the woman is  $\geq 18$  years of age; the woman has a singleton pregnancy and is at least 36 weeks' gestation; there is a negative antenatal screen for HIV and Hepatitis B; the woman is in labour and requires an assisted vaginal birth for a clinical indication (as per the Royal College of Obstetricians & Gynaecologists (RCOG) Greentop Guideline 26)(12); the RCOG specific requirements for AVB are fulfilled; 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 anesthetic) and there is no obstetric indication for an alternative method of AVB.

Women will not be able to take part in the ASSIST if: there is a diagnosis of a fetal skull abnormality precluding AVB (i.e. macrocephaly); there is a known osteogenesis imperfecta affected pregnancy; there is suspicion of a fetal bleeding disorder (von Willebrand's disease, AITP, haemophilia); there is an intrauterine fetal death in the current pregnancy; the woman is sensitive to latex; the woman is currently

servicing a prison sentence; the indication for AVB is a fetal bradycardia which is present, ongoing and has not recovered.

### *Intervention*

During the second stage of labour if the obstetrician attending an eligible woman, who has previously provided informed written consent to take part in the study, determines that an AVB is indicated, they will explain this to the woman as per standard practice. If the woman agrees to an AVB, an accoucheur who has had specific training in using the BD Odon Device (Additional file B) will assist the birth with the BD Odon Device. Should the birth not be achieved with the BD Odon Device, the accoucheur will use their clinical judgement on an individual case basis to complete the birth using ventouse, forceps or caesarean section as appropriate. Primary, secondary, safety and qualitative research data will be gathered regarding the assisted birth and use of the device.

### *Clinical, safety and process outcomes*

*Primary outcome.* Proportion of births successfully assisted with the BD Odon Device

A birth will be defined as 'successful' if all of the following six criteria are met (table 2).

### *Safety outcomes.*

Maternal:

- Weighed/measured blood loss in the first six hours following birth (postpartum haemorrhage  $\geq 3,000\text{ml}$ );
- 3<sup>rd</sup> or 4<sup>th</sup> degree tear;
- Cervical tear requiring suturing;
- Requirement for general anaesthesia;
- Shoulder dystocia;
- Use of emergency caesarean section to achieve birth;
- Maternal death.

Neonatal:

- Apgar score  $< 7$  at five minutes;
- Pressure necrosis of fat or skin;
- Neonatal soft tissue trauma (bruise/scalp/facial injury);
- Pressure necrosis of skin or fat;
- Neonatal vascular injury (haemorrhage/cephalohematoma/subaponeurotic haemorrhage);
- Neonatal skeletal injury (bone fracture);

- Neonatal intracranial injury (cerebral contusion);
- Neonatal neurological injury still present at 28 days after birth;
- Neonatal seizure;
- Phototherapy for jaundice contributed to by bruising;
- Death within 28 days after birth.

Device:

- Failure of a component of the BD Odon Device;
- Number of applications of device;
- Number of pulls with the BD Odon Device.

*Secondary outcomes.*

Clinical:

- Failure to achieve a vaginal birth with the assistance of the BD Odon Device and mode of birth thereafter;
- Method of infant feeding (day one, seven, 28 and 90 postnatal);
- Time from 'decision to perform assisted birth' to 'birth' (minutes);
- Time from 'device application' to 'birth' (minutes);
- Time to achieve regular respirations (minutes);
- Episiotomy and perineal trauma;
- Umbilical arterial and venous pH & base excess;
- Other neonatal injury;
- Neonatal pain (Neonatal Infant Pain Score (NIPS) at two and six hours after birth);
- Time spent in Neonatal Intensive Care Unit (hours);
- Anaemia requiring transfusion;
- Neonatal encephalopathy requiring therapeutic hypothermia within 28 days after birth;
- Organ failure within 28 days after birth;
- Failure to establish a normal feeding pattern: defined as  $\leq 1$  feed at ten hours of age.

Women-reported outcomes:

- Maternal health-related quality of life data (EQ-5D-5L) (antenatally at the time of consent, at day one and day 28 postnatal);
- Maternal satisfaction with birth experiences (Patient Perception Score on day one postnatal);
- Maternal perception of pain (day one, seven and 28 postnatal);
- Health service utilisation will be collected (day 28 postnatal);

- Maternal continence at 90 days.

#### Practitioner-reported outcomes:

- Willingness to use the BD Odon Device;
- Perceived overall ease of use of device;
- Ease of device set-up;
- Ease of device application to the baby's head;
- Ease of withdrawal of the applicator after application;
- Comfort with the level of force required to assist the birth of the baby;
- Ease of deflation of the air chamber prior to crowning.

#### *Safety of intervention*

A comprehensive assessment of the safety of the BD Odon Device will be undertaken following every attempted birth within the ASSIST Study. Outcome measures and data collected will ensure capture of any potential adverse events associated with the BD Odon Device at time of birth by the operator and/or a member of the research team (see Additional file A for details of case report forms). Follow-up will be performed by the research team. In the immediate postpartum period a member of the research team will follow-up the participant on a daily basis until discharge, collecting the day one data. To ensure that any serious adverse events that occur in the postnatal period are captured, an Adverse Event Reporting System will be initiated on the postnatal wards, for ward staff to highlight any serious adverse events that occur after discharge from labour ward. Postnatal staff will be asked to notify a member of the research team if any such events occur. In addition, device failure (or failure of any component) will be reported as an individual outcome measure. Follow-ups at day seven, 28 and 90 follow-ups will be conducted by a member of the research team telephoning the woman using their contact details provided to the study team. The Trial Management Group (TMG) and Sponsor will regularly review data from all births according to the schedule in Additional file C to ensure early identification of any trends of adverse events. All adverse events will be classified and reported according to the schedule of the Medicines and Healthcare Regulation Agency (MHRA) and the Research Ethics Committee.

*Recruitment and process outcomes.* To facilitate the development of the main trial, information will be collected on the number of women screened, identified as eligible, approached and consented to participate both in advance of labour and again during labour where applicable will be collected. Information on data completion, i.e. questionnaire completion, completion of main outcomes and missing data will also be reported. Reasons for ineligibility, participation refusal, lost-to-follow-up or missing data will also be explored.

#### *Patient and public involvement*

Women and their partners have been involved throughout the development of the ASSIST study. Formal patient and public involvement (PPI) panels have reviewed the proposed study design, patient-facing documentation (leaflets, videos and consent forms) and have supported both the general and specific aims of the study. The Trial Steering Committee (TSC) of the ASSIST Study includes a lay patient representative.

### *Sample size and analysis*

A complete sample size of 40 women will enable the estimation of the rate of successful assisted vaginal birth of 80% 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%.

### *Quantitative description*

The primary, secondary and safety data will be reported as frequency and proportion, mean (standard deviation) or median (interquartile range) depending on their nature and distribution. The overall rate of successful AVB birth will be reported and the frequency of unsuccessful births will be reported by the six criteria defined for success. Appropriate outcomes will be presented and broken down into subgroups by; operator experience (>10 years or <10 years), indication for assisted vaginal birth (fetal compromise or other indication of AVB), participant analgesia (regional anaesthetic or other analgesia), fetal station (0 and +1cm to spines or +2 and +3cm to spines) and fetal position (OA or OT or OP). The overall number of safety events will be reported, as well as the number of events, by main reasons for adverse events. Events related to the device failure and/or mis-use of the device will also be described.

The recruitment and process outcomes will be reported as frequencies and percentages. Completion rates of the clinical outcomes will also be reported. Reasons for ineligibility, refusal, lost-to-follow-up or missing data will be categorised and described as frequencies.

Data on numbers screened, identified as eligible, approached and consented to participate both in advance of labour and again during labour, where applicable included in follow-up and providing questionnaire and outcome data and successful birth rates, all will inform the sample size calculation of the main trial. During the trial, there will be a continuous review of mother and baby safety from the Sponsor and TMG, and a decision will be made as to whether to continue, revise or stop the trial.

Women and their babies will be followed up at one day, seven days, 28 days and 90 days following the birth. A woman and her baby will be deemed to complete their participation in the study at 90 days after the birth.

### *Integrated qualitative research*

Alongside the primary clinical study, an integrated qualitative study (IQS) within the feasibility study will be undertaken. This will investigate the practitioners use of the device, to ensure that an appropriate training package is developed for the trial; enable the intervention to be described and refined to optimise

its use; and to investigate the woman's, obstetrician's, midwife's and neonatologist's perspective of the birth and what they consider to be characteristics of a 'good birth'. This will enable the research team to incorporate these findings into any subsequent randomised controlled trial, as well as iteratively altering the ASSIST Study plan if required.

### *Trial oversight*

A Trial Management Group consisting of all investigators and co-investigators will be responsible for the day-to-day running of the study.

The study will be overseen by two committees, the Independent Data Monitoring Committee (IDMC) and the Trial Steering Committee (TSC). The IDMC will sit after 20 and 40 births have been completed and will have no direct involvement in the running of the trial. Following both reviews, the IDMC will generate a report on the performance of the device and safety of participants. These reports will be reviewed by the TSC and the Sponsor. The TSC will consist of an independent clinical expert, statistician and a lay representative, together with the investigators and representative. The TSC will review all reports produced by the IDMC and make a recommendation to the Sponsor following every review to continue, modify or halt the study. The TSC will provide oversight of the progress of the study and ensure the study is conducted according to the principles of Good Clinical Practice (GCP). Auditing will take place when requested by the Sponsor.

### *Dissemination*

Study results will be published within one year of completion of data collection in an appropriate peer reviewed open-access journal. The results will be presented at local, national and international meetings. Summaries will also be distributed using existing parent networks. A summary of results will also be sent to all women who participated in the study, unless they express their wish not to receive such information. Results will be communicated to a lay audience by social media activities of North Bristol NHS Trust, University of Bristol and the research team.

## **Discussion**

An appropriately conducted AVB, performed when clinically indicated, is associated with improved maternal and neonatal outcomes when compared to caesarean section in the second stage of labour, or no action(3). AVB is currently not performed in many low and middle income settings where it may be of significant benefit to individual woman and their babies in reducing birth-related morbidity and mortality(18). Current efforts to promote the use of AVB in these settings have been insufficiently effective, and may be due to the inherent limitations of the existing instruments. Therefore, the development of a new device for AVB is both justified and required(19).

The BD Odon Device is the first new device for AVB since the introduction of ventouse into clinical practice in the 1950s(20). Extensive pre-clinical simulation testing has suggested that it is not likely to

generate additional pressure over the fetal head compared to current instruments(13,21), is not likely to generate clinically significant levels of neonatal hypoxia if misplaced over the fetal carotid arteries(14), and is not likely to be associated with unsafe patterns of use by the target user population (16). We believe that it is therefore reasonable to proceed to a clinical feasibility study of the device, and, if positive, a randomised controlled trial.

If found safe by the TSC, IDMC and Sponsor, findings from this feasibility study will inform the design of a randomised controlled trial that may produce evidence that supports the introduction into clinical practice of a new device for AVB into clinical practice. If this were able to address the unmet need for AVB around the world it would have a major impact on the management of complications in the second stage of labour and maternal and neonatal outcomes worldwide.

## Abbreviations

AVB	Assisted Vaginal Birth
BD	Becton Dickinson
GCP	Good Clinical Practice
IDMC	Independent Data Monitoring Committee
IQS	Integrated Qualitative Study
LMIC	Low and Middle Income Countries
MHRA	Medicines and Healthcare products Regulatory Agency
NBT	North Bristol NHS Trust
NIPS	Neonatal Infant Pain Score
PPI	Patient and Public Involvement
RCOG	Royal College of Obstetrics and Gynaecology
RCT	Randomised Controlled Trial
TMG	Trial Management Group
TSC	Trial Steering Committee
UoB	University of Bristol

## Declarations

*Trial Status*

The ASSIST Study is scheduled to commence on the 8<sup>th</sup> October 2018, using version 16.10. The study will cease after 40 complete sets of primary outcome data are received. This is projected to be in May 2019.

Ethics approval and consent to participate

Informed consent will be obtained from all study participants.

All quantitative and qualitative aspects of the ASSIST Study have been approved by the South Central – Berkshire Research Ethics Committee, United Kingdom on 3<sup>rd</sup> September 2018, reference number 18/SC/0344. A certificate of non-objection was received from the Medicines and Healthcare products Regulatory Agency on 9<sup>th</sup> August 2018 and final approval from the Health Research Authority granted on 3<sup>rd</sup> September 2018 (Additional file D).

*Consent for publication*

Not required.

*Availability of data and materials*

All anonymised data and results of analyses will be available on a publicly-accessible database hosted by the University of Bristol – the DOI for this database will be made available in the results paper.

*Competing interests*

TD and SA have acted as consultants for Ferring Pharmaceuticals Ltd. EL is a member of University of Bristol (UoB) and part of his salary is paid by Prompt Maternity Foundation (PMF) to UoB; CW is employed by North Bristol NHS Trust and seconded to PMF; PMF has received funding from the Saving Lives at Birth Partners via a direct grant from Becton Dickinson (BD) for previously undertaken simulation studies of the BD Odon Device, these funds have been used towards the salary of SOB, TJD, JFC and CW when undertaking the simulation studies. TJD, CW and JFC have acted as unpaid consultants to Limbs and Things, Ltd, the manufacturer of the PROMPT Birth Trainer – the mannequin used for simulation training for the Odon Device. All other authors report no competing interests.

BD is providing the BD Odon Device for this study for no fee. They have no say in the design, conduct or interpretation of the study. Mario Meriardi, MD, Senior Director BD Global Health, provided information about the BD Odon Device and regulatory requirements that were incorporated in the protocol.

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*Authors' contributions*

JFC, TJD, CW and SOB conceived the idea for the study. JFC, TJD, CW, SOB, EL, EJH, JW, CR and AP developed the study and wrote the initial protocol. JFC, EJH, MA, MM, SH and SMK will run the study day-to-day. SOB, EJH, JFC and EL wrote the initial draft of the manuscript. All authors reviewed and approved the final manuscript.

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## Tables

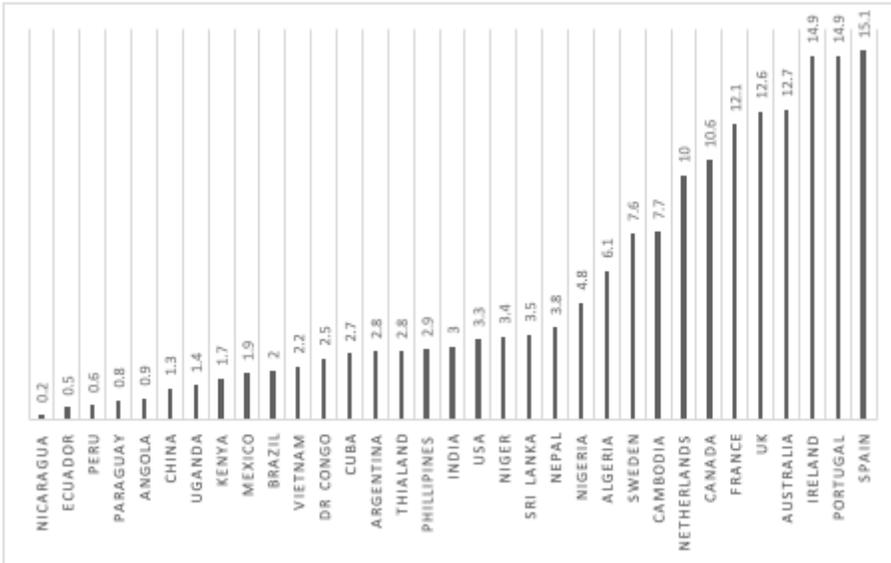
**Table 1** Schedule of enrolment, interventions and assessments

	STUDY PERIOD								
	Enrolment	Allocation	Post-allocation						Close-out
TIMEPOINT	Pre-recruitment	Point of requiring AVB	AVB	Day 1 PN	By Day 3 PN	Day 7 PN	Day 28 PN	Day 90 PN	Day 91 PN after the last delivery
<b>ENROLMENT:</b>									
Eligibility screen	X								
Informed consent	X								
Consent for audio-recording	X								
Allocation		X							
<b>INTERVENTION:</b>									
Attempted Odon Delivery			X						
<b>ASSESSMENTS:</b>									
Baseline characteristics	X	X							X
Delivery characteristics			X						X
Primary outcomes			X	X					X
Maternal outcomes			X	X		X	X	X	X
Neonatal outcomes			X	X	X		X		X

**Table 2.** Primary outcome

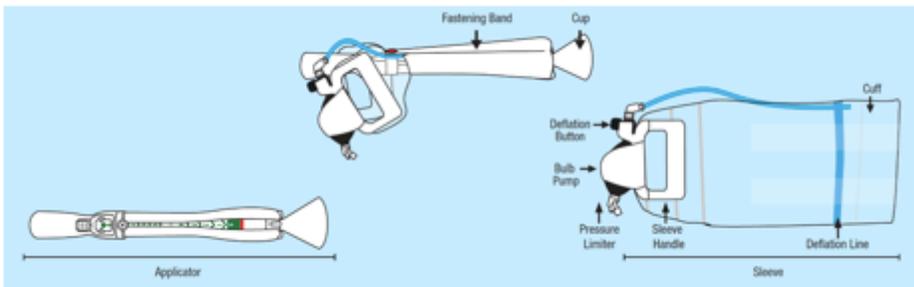
Criteria	Source	Collected by
The birth of the baby is expedited with the BD Odon Device forma	AVB pro Medical notes	Research team member including device operator
There are no serious maternal adverse events related to the use of the device during birth forma	AVB pro Medical notes	Research team member including device operator
There are no serious neonatal adverse events related to the use of the device during birth forma	AVB pro Medical notes	Research team member including device operator
There are no serious adverse device effects forma	AVB pro Medical notes	Research team member including device operator
The woman's perception of her birth is rated above a score of 6	Case report form	Research team member
The practitioner reported outcome is above 12.	Case report form	Device operator

## Figures



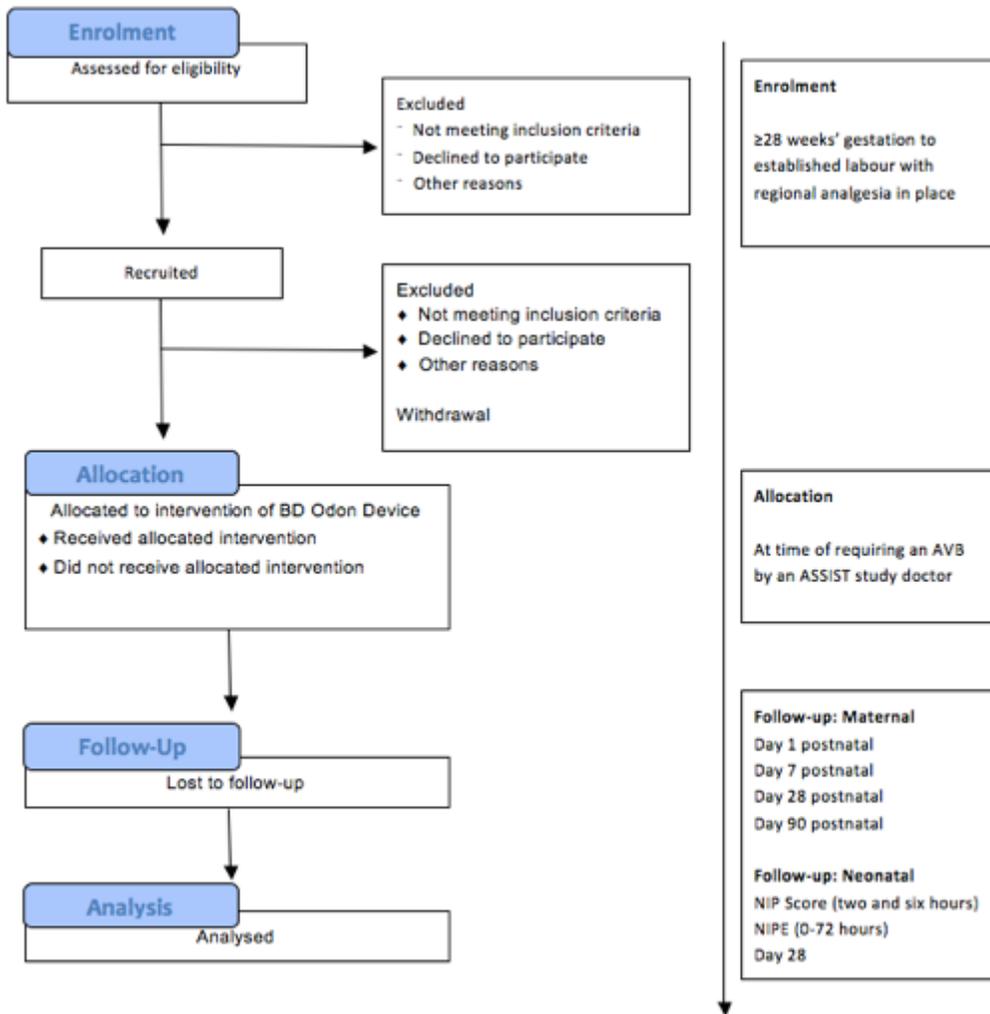
**Figure 1**

Rates of AVB in selected countries 2005 - 2016.



**Figure 2**

The BD Odon Device component parts (image reproduced with permission of BD).



**Figure 3**

CONSORT diagram of ASSIST feasibility study.

## Supplementary Files

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