



North Bristol
NHS Trust

ASSIST II



ASSISTED VAGINAL BIRTH STUDY

**The BD Odon Device™ for assisted vaginal birth:
A feasibility study to investigate safety and efficacy
The ASSIST II Study**

Participant Information Leaflet

Would you be willing to join us in a research project?

The ASSIST II Study:

A study investigating the use of a device that may be used to assist a baby's birth

We would like to invite you to join us in a research study investigating a new device which may be used to assist your baby's birth. Before you decide whether you would like to participate, it is important for you to understand why the research is being performed and what it involves. There is also an ASSIST II Study video – the video and this leaflet contain different information so it is important they are used together. You will then be able to ask any questions and be given time to decide if this study is right for you and your baby.

Why have I been invited to take part?

All women who are pregnant with one baby and are planning a vaginal birth at either Southmead or Cossham Maternity Unit are invited to take part in this study. If you would like to take part, we would like your agreement in principle before labour, just in case you do need assistance with the birth of your baby later on.

Do I have to take part?

No. It is entirely up to you whether you agree to take part or not. If you decide not to be involved, your care will not be affected in any way. Even if you do agree you can always change your mind and withdraw at any time, without giving a reason.

What is the purpose of the ASSIST II Study?

This study is investigating a new single-use device - the BD Odon Device, also known simply as the 'Odon'. Instead of using a suction cup (ventouse) or metal forceps on the baby's head, the Odon uses an inflatable air cuff. You can see a demonstration of the Odon in the information video.

The aim of this study is to determine how effective and acceptable the Odon is and how safe it is for mothers and babies, so that we can plan future developments and compare it to the other devices in future research.



Effectiveness – How helpful is the Odon to women and babies needing an assisted vaginal birth?



Acceptability – What do the mothers think of the Odon when it is used in their labour, and how do the Doctors and Midwives feel about it?



Safety – How safe is the Odon for mothers and babies?

If successful, this study and previous Odon research will help the device manufacturer apply for a CE mark which is a quality assurance mark like a 'Kite Mark'.

What will happen if I agree to take part?

Your antenatal care and care in labour will be no different to usual.

If you do need an assisted vaginal birth at the end of your labour, and if it is appropriate, a Doctor will assist your birth using the Odon, instead of ventouse or forceps. Birth with an Odon does not take any longer than with the other devices and as with any birth (except emergency situations) you will be able to have delayed cord clamping and skin-to-skin contact with your baby.

There are some situations where you may still need an assisted birth but it would not be reasonable or possible for us to use the Odon. This may be due to your baby needing to be born urgently, the position the baby is lying in, or if an Odon-trained Doctor is not available. If this happens, or if the Odon has been unsuccessful, then your Doctor will use their clinical judgement and experience to decide how best to assist the birth of your baby, just as they would for any other assisted birth.

A Research Midwife may be present to assist your Midwife and Doctor during and following the birth of your baby.

After your baby has been born, the rest of your care will proceed as usual for both you and your baby, but with some additional care from the Research Team. We do not expect you to have to stay in the maternity unit for longer because you are participating in the study.

If you consent to participate in the study, but the Odon is not used to deliver your baby, we may still call upon you and/or use your data.

Will participating in the study take up lots of my time?

We have designed the study to take as little extra time as possible.

If you agree to take part and have an assisted vaginal birth the following checks will take place in addition to your routine care:

Before labour	•One short questionnaire
The day your baby is born	•Assessment of your baby at 2 and 6 hours old
1 day after birth	•Assessment of your baby plus two short questionnaires
7 days after birth	•One short questionnaire
28 days after birth	•Two short questionnaires
90 days after birth	•One short questionnaire

Each contact will take about **5-10 minutes**. Whilst you are in the maternity unit, this will be in person. After you have been discharged we will contact you by phone or video call. We may text you before to remind you we're about to get in touch, and if we can't reach you directly, we'll post or email the questionnaires to you. A Neonatal Consultant will also review your baby's notes at 28 days (you don't need to be present for this).

What are the possible benefits of taking part?

There may be no direct benefit to you or your baby. We believe that the new device is safe but at this stage we really do not know whether it is better than the ventouse or forceps, or even what 'better' means.

So, the main benefit will be helping us with the design and conduct of the next phase of the study and possibly helping women and babies who might need an assisted vaginal birth in the future.

You will be contacted by the study team following the birth, in addition to your routine care. Many women who have participated in other maternity research studies run by North Bristol NHS Trust have found this extra contact useful in the weeks after their baby's birth as you will have the additional opportunity to speak to a Midwife about how you and your baby are.

What are the possible risks of taking part?

In a similar way to the ventouse, the Odon device may not always be successful at completing the birth of the baby and another device (for example Forceps) may need to be used. During the first ASSIST Study, at Southmead Maternity Unit in 2018 and early 2019, the Odon device was used in 40 women who required an assisted vaginal birth. The Odon was successful in completing the birth in 19 of the 40 cases (48%). Changes to the way we use the device have meant that in the early stages of the current study (ASSIST II), the device has helped more women give birth compared to the first ASSIST Study - between 60 and 80% of the babies were born using the Odon. A similar study is underway in France with similar results.

All births carry risks (such as tears or heavy blood loss for mothers, and bruising or shoulder dystocia to baby). We know that the possibility of

these happening can increase when any assistance with the birth is required. We are monitoring all birth outcomes very closely as it is not yet known if the risks are any different when the Odon is used, compared to the ventouse or forceps. With the information we have so far, we know there have been no unexpected problems to mothers or babies when using the Odon compared to the ventouse or forceps.

In order to reduce the risk of a severe tear it is Hospital practice to assess any women having an assisted vaginal birth for an episiotomy (a small cut to the perineum). Your Doctor will discuss this with you. Additionally, all women who have an assisted vaginal birth (using any of the devices) are given a dose of antibiotics following birth to reduce the risk of infection.

What happens when the ASSIST II Study finishes?

We will publish our results nationally and internationally, so that other healthcare professionals can learn from our results and help to improve care in labour for women and their babies. We will write to study participants with a summary of the findings. If the results are encouraging, then the findings will help us design the next phase of research.

Can I become more involved?

Yes please. Receiving your feedback is extremely important to us. If you give your consent, we may invite you to participate in 'Parent and Public Involvement'. This will give us a chance to listen to your views and ideas, with the aim of improving research and the maternity care provided to women and their babies during birth. Involvement may be in person or by email, phone or video-call, depending on your preferences.

How will my information be used?

We will use information from you and your baby, and from your medical records. We will keep all information safe and secure.

Information we store will include your names, contact details, and NHS number. Research staff will use this information to conduct the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

Some of your information will be sent to the manufacturer of the Odon device. They must follow our rules about keeping your information safe. We will also write to your GP to inform them of your participation in the study. If we discovered that you or your baby is at risk of harm, we may need to inform someone to get you the help that is needed. This is obviously unlikely and we would always talk to you first and encourage you to seek help for yourself.

What are my choices about how my information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. We need to manage your records in specific ways for the research to be reliable. This means that we will not be able to let you see or change the data we hold about you. If you agree to take part in this study, the data about you and your baby may be used to support future research.

You can find out more about how we use your information:

- at www.hra.nhs.uk/information-about-patients/
- via our leaflet at www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by emailing the Sponsor's Data Protection Officer
Helen.E.Williamson@nbt.nhs.uk

What if there are any problems?

NHS-sponsored research studies such as this one are covered by NHS indemnity (the same indemnity that applies to any patient in the NHS). In the unlikely event that you feel that you or your baby has been adversely affected by participating in this study, you should contact the research team as soon as possible. The team will arrange to meet you to discuss your concerns. Should you wish to complain about any aspect of the way you have been approached or treated during the course of this study, the normal NHS complaints mechanisms will be available to you.

Please visit www.nbt.nhs.uk/patients-carers/feedback for further information or contact the North Bristol Trust Hospital Patient Advice and Liaison Service (PALS) on **0117 414 4569**. PALS can also provide confidential advice and support to patients, families and their carers.

How is the study funded? The Bill & Melinda Gates Foundation have funded this research as part of the Odon Programme.

Grant number: INV-010180

Who is conducting the study? Professor Tim Draycott (Consultant Obstetrician) is the Chief Investigator and Dr Jo Crofts (Consultant Obstetrician) is the Principal Investigator. North Bristol NHS Trust are the study Sponsors.

Who has reviewed the study? The South Central, Berkshire Research Ethics Committee has reviewed and agreed this study (Ref 19/SC/0226).

What do I do now?



Visit the **ASSIST II Study website to find out more**

The website has more information about the study including videos demonstrating the device on a model and some feedback from previous participants. Scan the QR code or go to www.nbt.nhs.uk/ASSISTII .



Remember – it's your choice

As there is a lot of information to understand, we would like to give you as much time as possible to think about whether you would like to be involved and to discuss it with your birth partner, Community Midwife, friends or family. Making decisions during labour can be difficult and mothers previously involved in the study have said they have found it beneficial to speak with a Research Midwife before labour.



How to become involved

If you would like to take part in the study you can register your interest via our website or get in touch directly via email or telephone. We can offer you an appointment to discuss participation by telephone or video-call or in person at the Women's & Children's Research Hub at Southmead Maternity Unit

If you prefer, we can discuss the study at an antenatal appointment or when you arrive at the Hospital for your delivery. We may approach you if it is appropriate, or you can ask to speak to a Research Midwife once you've settled in.

Get in touch

Call **0117 414 6764** during normal working hours

Email assist@nbt.nhs.uk at any time

Or, **register your interest** on the website and we will get in touch with you

