Patient information sheet

IMox: A study comparing three medicines used for the "active management of the third stage of labour" (to help deliver the placenta after your baby has been born).

We would like to invite you to take part in our research study. Before you decide whether you would like to participate, we would like you to understand why this research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have.

Firstly, some information about your labour…

The third stage of labour is the period of time between the birth of your baby and the delivery of your placenta. You have a choice about whether you would like to have a natural or "physiological" delivery of your placenta, or whether you would like "active management" of this stage of labour, which is called the "third stage of labour" Our study would only apply to women wishing to have an "active management" of the third stage of their labour.

"Active management" of the third stage of labour

This involves a one-off injection in your leg just after your baby is born and the umbilical cord has been clamped, and before the placenta being gently delivered by the midwife or doctor. The medicine is given to reduce the risk of you experiencing heavy bleeding (haemorrhage), reduce the need for extra medicines to make your womb contract well, and reduce your need for a blood transfusion after your baby has been born. Having this injection also makes the "third stage of labour" shorter.

Women may choose "active management" if they want to reduce the risk of heavy bleeding. In certain situations your doctor or midwife might advise that you have the third stage of labour managed "actively" in this way, for your safety.

Choosing "active management" does not harm your baby in any way. Previous studies comparing "physiological" and "active" management of the third stage of labour have found that babies born after an actively managed third stage of labour are no more likely to need admission to the baby hospital, and are no more likely to experience jaundice or require treatment for this.

What is the purpose of the study?

We want to find out which of three medicines is best for the "active management" of the third stage of labour for women having a vaginal birth. These medicines are **Syntocinon**, **Syntometrine** and **Carbetocin**. All of these medicines are safe to use and are already being given to women for delivery of their placenta. Our study will find out which medicine is best at reducing blood loss and which allows women to feel as well as possible in the first hours after birth. We also want to compare the overall cost of these three medicines, to help the NHS spend its money most effectively. Knowing all

of this information will help midwives and doctors to provide the best possible care for mothers giving birth.

Syntometrine	• Syntometrine is routinely used for active management of the third stage of labour after vaginal birth in all hospitals participating in this study, and in the majority of maternity units in the UK • When compared with Syntocinon, Syntometrine is slightly more effective at preventing "mild" bleeding • Syntometrine and Syntocinon are equally effective at preventing "major" bleeding • Syntometrine can sometimes make you feel or be sick – this affects less than a quarter of women, and it can sometimes raise your blood pressure for a short time after birth
Syntocinon	• This medicine is usually used instead of Syntometrine, when a woman has high blood pressure • Syntometrine and Syntocinon are equally effective at preventing "major" bleeding • Syntocinon is less likely to make you feel or be sick – this affects less than one in ten women
Carbetocin	• This medicine is currently only used after caesarean section, where it has been found to be better than other medicines at preventing heavy bleeding. This is why we want to carry out this study – to see whether it is also better after vaginal birth. • Some small studies comparing Carbetocin with Syntometrine, and Carbetocin with Syntocinon have already been conducted. These studies have found that Carbetocin may be associated with less bleeding after birth, and less women feeling or being sick.

No studies have compared all three medicines for effectiveness and side effects and this is what we would like to do, with your help.

Why have I been invited?

All pregnant women who are pregnant with a single baby and are planning for a vaginal birth, and active management of the third stage of labour, are being invited to take part in this study. However, if your baby is born by caesarean section then you will no longer be able to take part in this study. Also, if you have high blood pressure, you will not be able to participate. Your midwife or doctor will be able to answer any questions you might have about whether you are able to take part in this study.

Do I have to take part?

It is entirely up to you whether you join this study or not. If you agree to take part, you will be able to change your mind at any time.

What will happen to me if I take part?

If you decide to take part in this study, the clinical care you receive up to the time of this injection, and afterwards, will be almost exactly the same as it would be if you were not taking part in this study. The only slight difference to routine care may be the timing of when this one injection is given. Some hospitals routinely give this injection as soon as the baby's shoulders are born, while

other hospitals wait until the whole of the baby has been born, or until after the cord has been clamped. In this study we routinely wait until whenever the cord has been clamped. Your midwife or doctor will be able to advise you about what happens routinely at your hospital. All of these options are safe for you and your baby.

If you decide to take part in this study, you will be given one of either Syntocinon, Syntometrine or Carbetocin as a one-off injection in your leg. Whether you receive Syntocinon, Syntometrine or Carbetocin will be decided by a computer. The computer will allocate treatment randomly. This means by chance, like tossing a coin. You will not know which you have received, and neither will the doctors or midwives looking after you. (Although they will be able to find out if they ever need to know.) After you have received the injection your placenta will be delivered by the midwife or doctor in the usual way, by gently pulling on the umbilical cord once your womb has started to contract.

Skin to skin contact, cord clamping and hospital stay

You will be able to have skin-to-skin contact with your baby as soon as they are born, and you will also be able to ask that the cord is not clamped straight away after birth. However, there may be some situations in which it is medically necessary to clamp and cut the cord quickly after birth (i.e. if there were concerns about your baby's wellbeing immediately before or after birth)

Participating in this study will not mean that you have to stay longer in hospital after the birth of your baby. However there may be other medical reasons why you have to stay in hospital.

Will there be extra paper work for you to fill in?

The midwife or doctor looking after you will collect information on any bleeding after birth, how well your womb has contracted, whether you needed any extra medicines, and your blood pressure measurements.

You will be asked to complete a simple "maternal experience" questionnaire approximately two hours after your baby is born. This will ask you how you have felt, and bonded with your baby, in the first two hours after your baby's birth. The questionnaire should only take about 5-10 minutes to complete, and the midwife can read the questions out to you if you would prefer.

You will also be asked to fill out a "health-related quality of life" questionnaire. This only contains 5 questions and should only take 5 minutes to answer. You will be given a paper copy of the questionnaire 1 day after your baby's birth. You will also be phoned by one of the study researchers 2 weeks after your baby is born, and asked the same 5 questions on the phone.

What will happen to me if I decide not to take part?

If you decide not to take part, this will not affect the standard of care you receive. If you decide not to take part and would still like active management of the third stage of labour, you would receive the standard medicine used in the hospital where you are giving birth.

What are the side effects of any treatment received when I take part?

All three medicines being compared in this study are safe to use and are already being given to women for delivery of their placenta. The side effects of Carbetocin and Syntocinon are similar. Between one and four out of every ten women may experience feelings of sickness, tummy pain, itching, feeling flushed, feeling of warmth, lower blood pressure, headache or tremor. Between one and five out of a hundred women may experience back pain, dizziness, metallic taste, anaemia, sweating, chest pain, breathlessness, chills or fast heartbeat.

Syntometrine is similar in its side effects, but is slightly more likely to make you feel or be sick. This happens to less than one in four women. Occasionally, it can also give you temporarily high blood pressure. If your midwife or doctor have concerns about your blood pressure being high at any time after you have consented to participate, you would be withdrawn from this study as we would not want you to have Syntometrine.

The primary concern of your doctors and your midwife is the safety of both you and your baby at all times.

Will it affect my baby?

Taking part in this trial will not affect your baby in any way.

What are the possible benefits of taking part?

The information we gain from this study will help to ensure that women are given the best care during the third stage of labour. We will also collect vital information from mothers about their experience of birth. This will help us to provide the right information and choices, and to ensure an even more positive birth experience for new mothers in the future.

What happens when the study stops?

Once this study finishes, we will analyse all of our results to try and find out which is the best medicine. We will then aim to publish our results nationally and internationally, so that other hospitals and countries can learn from our results too.

What if there are any problems?

In the very unlikely event that you are harmed by taking part in this research project, there are no special compensation arrangements. NHS-sponsored research studies such as this one are covered by NHS indemnity (the same indemnity that applies to any NHS patient). If you want to complain about any aspect of the way you have been approached or treated during the course of this study, then the normal NHS complaints mechanisms will be available to you. Please visit www.nbt.nhs.uk/patients-carers/feedback for further information about how to make a complaint, or contact the North Bristol NHS Hospital Patient Advice and Liaison Service (PALS) on 0117 323 3741. PALS can also provide confidential advice and support to patients, families and their carers. Further contact details for PALS are listed below under “Further information and contact details”.

Who has reviewed the study?

The South Central – Oxford B Research Ethics Committee has reviewed and agreed this study (Ref 14/SC/1312)

What do I do now?

If you are interested in taking part in the study, inform your midwife or doctor when you next come to the hospital, or tell your community midwife when you next see her.

Further information and contact details

If you would like more information about this study, please contact the midwife or doctor providing your care, or the North Bristol Trust Maternity research team **0117 414 6764.**

Please email imox@nbt.nhs.uk if you wish to be informed of the results of this study once it has been completed.

The North Bristol NHS Trust Hospital Patient Advice and Liaison Service (PALS) can be contacted on

- Telephone **0117 414 6764**
- Email **complaints@nbt.nhs.uk**
- **www.nbt.nhs.uk/patients-carers/feedback**