



DEXmedetomidine Trial of Adjunct Treatment with Morphine Parent Information Sheet

**Your baby is invited to take part in
our research trial**

- DEXTA will explore whether using dexmedetomidine (“dexmed”) in addition to morphine can reduce the total amount of morphine needed for babies who are born early (premature) and need a ventilator to help with their breathing.
- This information sheet is to help you understand why the research is being carried out and what it will involve for you and your baby, if you decide to allow your baby to take part.

**Please take time to read this information and ask us if there is anything that
is not clear or if you would like more information.**

- It is entirely your decision whether your baby takes part in this trial.
- If you agree for your baby to take part, you are free to withdraw them at any time without giving a reason.
- If you choose not to take part, your baby’s care will continue in the usual way.

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What is DEXTA?

A summary of the trial

Your baby was born early and needs specialised neonatal care to ensure their wellbeing. As part of this care, your baby will receive additional support with their breathing, which is given using a breathing machine called a ventilator. Being on the ventilator can be painful and babies are given pain relief using morphine.

Morphine relieves pain and keeps your baby comfortable, but some studies have shown that large doses of morphine can have side effects, such as delaying feeding, slowing breathing, extending time in intensive care, and it may have a harmful impact on brain development and behaviour in later childhood. We are, therefore, investigating other medicines that could relieve pain in babies so that we can keep babies pain free with smaller amounts of morphine and reduce its harmful effects.

One such medicine is dexmed, which is used for pain relief in children and adults, with smaller studies using dexmed in babies. These studies suggest that dexmed could relieve pain with fewer side effects and be better for brain development.

What is the aim of the trial?

The aim of DEXTA is to investigate, in ventilated preterm babies, if one of two different doses of dexmed given in addition to the usual dose of morphine, reduces the amount of morphine needed to keep the baby pain free and reduces the possible harmful effects of morphine.



Why has your baby been invited to take part?

Your baby has been invited to take part because they:

- were born more than 8 weeks early (<32 weeks' gestational age at birth)
- are expected to need at least 48 hours of ventilation
- are receiving or may require morphine infusion

We are inviting 240 babies from neonatal units across the UK to participate.

Does your baby have to take part?

You decide whether or not your baby takes part.

Even if you agree now, you are free to withdraw your baby later. We will talk to you about the trial and answer any questions you may have. If you agree to take part, we will ask you to sign a consent form.

What taking part involves?

DEXTA has been designed so that only the minimum amount of data required for answering the research question is collected. This will include information collected by the hospital and additional questionnaires for parents to complete. Each is important to the trial and will help show if Dexmed can be used to reduce the amount of morphine needed to keep babies pain free and reduce adverse effects.

More information on what taking part would involve and how information on your baby is used is explained in more detail on pages 4/5/6 & 8.



Shopping voucher

With the questionnaire sent to you when your baby is 2 years of age, we will send you a £20 voucher (by post or via email or text as per your choice), as a thank you for your involvement in the trial.

What taking part involves?

Trial treatment

If you decide that you want your baby to take part in DEXTA, healthcare providers in your hospital will check your baby's medical records to ensure they are eligible to take part. After this, if you wish for your baby to take part, you will need to sign a written informed consent form. If you provide written informed consent and your baby is then found to be not eligible, they will not be included in the trial and their care will continue as decided by your baby's doctor. A member of the research team will inform you if this is the case.

To fairly compare the treatments, we will randomly assign babies to groups that are alike in all aspects except for the treatment they receive.

If you agree and give your consent, your baby will be assigned to one of 3 groups (called trial arms) and be given one of three different treatments:

- 120-hour infusions of dexmedetomidine (0.5mcg/kg/hour) + morphine
OR
- 120-hour infusions of dexmedetomidine (0.25mcg/kg/hour) + morphine
OR
- 120-hour infusions of matched placebo (a dummy medicine) + morphine

What treatment will my baby receive?

We do 'randomised trials' when there is more than one treatment option, and we don't know which one is the best. To find out, we compare the different treatments by putting babies into groups. Which of the three groups your baby is put in will be decided randomly using a computer programme. This is called "randomisation." It means your baby will have an equal chance of receiving one of the three treatments. The dummy medicine is safe, and will have no effect on your baby.

You and your baby's neonatal care team will not know which one of these three groups your baby will be in. This is called "blinding". It ensures that other decisions made about your baby's care are not influenced by the trial and keeps the trial from being unduly affected by anyone's biases.

Randomisation and blinding allow for a fair comparison of all 3 treatment groups.

What taking part involves?

Receiving the treatment

The trial medicine will be given for 120-hours (5-days). In this period, we will collect information on your baby's pain levels, amount of morphine they get (this is only given when there are signs of pain), and other information such as their heart rate and blood pressure. We want to see if dexmed reduces their pain and the amount of morphine they are given.

On the second, third and fourth day of having the trial medicine, we will collect a small amount of blood (0.3-0.5 ml) from your baby. The blood sample will be taken at a time when they are already having a blood test for their usual care. Your baby will not have any additional blood tests separately for the trial. The blood sample will help us understand how your baby's body processes dexmed.

Once the 5 days are completed, your baby will not be given any more medicine for the trial. They will only receive the care advised by your hospital.

Following your baby's progress

Your baby will receive some additional monitoring to help us understand the impact of the treatment on their time in hospital, and their health over the next two years.

When your baby reaches the age when your pregnancy would have been 36 weeks, or when they are ready to go home (whichever is later), we will collect information about your baby's health, their time in neonatal care and feeding. We will also ask you to complete a questionnaire asking about your experience of the trial.

After you go home, with your consent, we will keep in touch and send your baby birthday cards.

When your baby reaches the age of 2 years corrected for prematurity (i.e., 2 years from your due date) we will send you another questionnaire asking about your baby's health and development. This questionnaire can be sent to you online, by post, or can be completed over the telephone. The information on this questionnaire will be used by the trial to make an informed decision on how well dexmed, used alongside morphine, can improve outcomes for babies born early. This questionnaire is an important document for the trial.

If you agree to this on the consent form, your name and telephone number may be shared with Esendex, our text messaging provider and their subprocessors, and be used to send you text message reminders about the trial and trial questionnaires whilst you are participating in the trial should that be necessary.

What happens to the blood samples from your baby?

We will collect blood samples (0.3 to 0.5 ml) on three days after starting the trial medicine. These samples will be taken while your baby is having routine blood sampling and will be sent to Analytical Services International, based in St George's at the University of London, for analysis. If any sample remains after testing, it will be retained for 6 months after trial finishes and will then be destroyed.

To give some reassurance, 0.5 ml of blood is about one-tenth of teaspoon, and is well within the safe limit.

We refer to blood sample collection throughout this information sheet. However, this part of the trial will not apply to all participants.

Blood samples will only be collected from the first 120 babies who are enrolled and provide a sample. Once we have reached this number, no further blood samples will be needed or collected for the trial. A member of the research team at your hospital will tell you whether your baby will have blood samples taken as a part of the trial.

What are the possible disadvantages and risks of taking part?

Dexmed, similar to other medicines, may cause side effects in some babies. The most common side effects of dexmed are lowering of the heart rate and blood pressure. Studies done so far show that the fall in heart rate and blood pressure are not likely to cause harm.

During the 120-hours your baby will get the trial medicine, the clinical team will measure your baby's heart rate and blood pressure regularly. If they have any serious concerns, they will stop the trial medicine.

A full list of treatment side effects and contraindications can be found here



What are the possible benefits of taking part?

Taking part in the trial may not directly benefit your baby, but the information we collect from this trial may help us to treat other babies who are ventilated in the future.

Your Choices as a Parent

Consent

Whether or not your child takes part in DEXTA is completely your choice. Your care and the care of your baby will not be impacted in any way from refusing to take part. If you do wish for your baby to take part:

- You will be asked to sign a consent form to agree for your baby to take part in the trial.
- You can also indicate on the consent form if you are happy to be contacted in the future about your baby taking part in further research studies.
- With your consent, your name and telephone number will be shared with Esendex, our text messaging provider, and their sub-processors. They will be used to send you text message reminders about the trial and questionnaires about your baby's health.

What are your choices about how your baby's information is used?

- Your baby can stop being part of the trial at any time, without giving a reason, but we will keep information about your baby that we already have.
- If you choose to stop your baby from taking part in the trial, we would like to continue collecting information about your baby's health from their neonatal care team. If you do not want this to happen, tell us and we will stop.
- You have the right to ask us to access, remove, change or delete data we hold about you and your baby for the purposes of this trial. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your baby's data to do the research. If so, we will tell you why we cannot do this.
- If you agree to take part in this trial, you will have the option to take part in future research using your baby's data saved from this trial.

What will happen if you don't want to carry on with the trial?

You are free to withdraw at any time, without giving any reason, and without your and your baby's legal rights being affected. If you would like to withdraw, contact your local researchers / NCTU Trial team and they can organise this for you. Their contact details are at the end of this information sheet. If you withdraw the information collected will not be erased and this information may still be used in the project analysis.

How will we use information about you and your baby?

We will need to use information from your baby's medical records for this research project. This information will include:

- your baby's initials, NHS number and name

AND

- your contact details (address, email, telephone number)

People will use this information to do 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 or your baby are will not be able to see your name or contact details. Your and your baby's data will have a code number instead.

University Hospitals of Derby and Burton NHS Foundation Trust is the sponsor of this research and is responsible for looking after your information. We may share your information related to this research project with the following types of organisations: NHS bodies, The DEXTA research group and Regulatory authorities. We will keep all information about you safe and secure by:

- Following and adhering to the laws relating to General Data Protection Regulation (GDPR) and complying with our Sponsor data protection policies
- Having strict access controls on our electronic systems
- Deleting your personal data (as outlined in this information sheet) when it is no longer required
- Keeping the details we have to contact you separate from the trial data

International Transfers

Your data will not be shared outside the UK.

How will we use information about you after the trial ends?

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

We will keep your trial data for a maximum of 15 years. The trial data will then be fully anonymised and securely archived or destroyed.

Where can you find out more about how your information is used?

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



by sending an email to our Data Protection Officer at uhdb.dataprotectionofficer@nhs.net



by reading our privacy statement: <https://www.uhdb.nhs.uk/privacy/>



by asking a member of your local maternity research team



by sending an email to DEXTA@nottingham.ac.uk



by calling the Nottingham Clinical Trials Unit on 0115 74 85 885

Or by visiting the following websites:

- HRA website: www.hra.nhs.uk/patientdataandresearch
- Nottingham Clinical Trials Unit data protection page: <http://www.nctu.ac.uk/data-protection/data-protection.aspx>



Trial organisation

Who is organising and funding this trial?

DEXTA is organised by the University Hospitals of Derby and Burton NHS Foundation Trust (the Sponsor) and coordinated by the Nottingham Clinical Trials Unit at the University of Nottingham. The funding for the trial is provided by the National Institute for Health and Care Research, which is the research part of the NHS.

How has it been reviewed and approved?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your baby's interests. This trial has been reviewed and given favourable opinion by a Research Ethics Committee.

Parents of babies who have received neonatal care and needed pain relief have helped us plan and design this trial. Parent representatives, including the national charity Bliss, are closely involved in the design and running of the trial. They provide valuable input on parent experiences and help ensure the trial is carried out in a way that supports families and reflects their needs.

What if relevant new information becomes available?

Sometimes we get new information about your baby's treatment during the trial. If this happens, your baby's doctor will tell you about it and discuss whether your baby should continue in the trial. If you decide not to carry on, your baby's doctor will make arrangements for your baby's care to continue as normal. If you decide to continue in the trial, they may ask you to sign a new Informed Consent Form.

What happens at the end of the trial?

When the trial ends, your baby's care and treatment will continue as normal.

At the end of the trial, the results will be published in scientific medical journals and presented at conferences. Your baby will not be identified in any publication. If you consent to receiving this, we will send you a newsletter with a summary of the trial findings.

Contact details

Contact details of your local care team who will be your main point of contact for the duration of the trial:

<contact details.
<contact details>
<contact details>

What if there is a problem?

If you have concerns or questions about any aspect of this trial, you should ask to speak to the local researchers. Their contact details are above.

If any questions remain you can contact the trial coordinating centre:

Tel: 0115 74 85 885

Email: DEXTA@nottingham.ac.uk.

If you remain unhappy and wish to complain formally, you can do this through the National Health Service (NHS) Complaints Procedure via your local Patient Advisory and Liaison Service (PALS)

<insert Local PALS details>

In the unlikely event that something does go wrong and your baby is harmed during the research then you may have grounds for a legal action for compensation but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.