Measuring Oxygenation in Newborn Infants with Targeted Oxygen Ranges

Parent Information Leaflet

Monitor – Parental Information Leaflet
Version 2 – 27 Nov 2017
194632

We understand that this is a difficult time for you and your family and it may not seem a good moment to be talking about research. However, we think it's important to tell you about a study taking place in this hospital for babies who have been born early.

What is the purpose of this study?

We are still learning what levels of oxygen premature babies need – both too little oxygen or too much oxygen in the first weeks after birth may be harmful. The best evidence so far has been from 5 big studies involving neonatal units in the UK, Australia, New Zealand, America and Canada. These used oxygen saturation monitoring – a small probe which shines light through the skin and calculates how much oxygen is carried in the blood.

These studies showed that if babies were targeted to a higher oxygen saturation range (91-95% rather than 85-89%) in the weeks after birth, more babies survived and fewer babies suffered from a bowel condition called necrotising enterocolitis (NEC). Targeting oxygen higher increased the number of infants who needed treatment for an eye condition called retinopathy of prematurity (ROP).

The two oxygen saturation target ranges (91-95% compared to 85-89%) in these studies are the only ranges that have been investigated in depth. It is possible that a saturation range a little higher than 91-95% would be associated with even better survival in preterm babies. It is also possible that a higher range might not improve survival but could increase the need for ROP treatment without other benefits. Our unit currently uses the range 90-95%, but we would like to measure the effect of targeting babies to a slightly higher oxygen saturation target range (92-97%) for a brief period (6 hours).

We want to show what oxygen levels are achieved by premature babies targeted to a slightly higher oxygen range of 92 to 97% so that we can plan a future larger study of the effect of this on clinical outcomes. We are confident that these oxygen levels will not be

dangerously high, and to provide an additional measure of this we would also like to put an additional monitor on your baby (called a transcutaneous monitor).

This study will not be big enough to assess health outcomes. It will give us the information that we need to plan a larger study of higher oxygen target limits for premature babies which would be big enough to assess outcomes. We also want to gather as much information as possible about the two different ways of measuring oxygen levels to see whether we need one or both for our future studies.

Why have I been invited to take part?

We are inviting parents of babies born more than 11 weeks early to allow their babies to take part in this study. This is because we are still learning what levels of oxygen premature babies need. We hope this study will help us find out this information.

Does my baby have to take part?

Whether or not your baby takes part is completely up to you. A doctor or nurse taking care of your baby will discuss the study with you and ask one of the research team to come and speak to you if you have any further questions. Your baby's care will not be affected in any way if you decide you do not want your baby to take part in the study. If you decide you would like your baby to take part, you can change your mind at any time and withdraw your baby from the study without giving a reason.

What will happen if my baby does take part?

This study doesn't involve any extra blood tests. For 12 hours after your baby is 2 days old, and while they are still getting oxygen, we would monitor their blood oxygen levels with both a saturation monitor and a transcutaneous monitor. These monitors attach gently to the

Monitor – Parental Information Leaflet
Version 2 – 27 Nov 2017
194632

skin. Both kinds of monitor have been in common use in premature babies for many years.

For 6 hours we would set the oxygen saturation target range to be 92 to 97%, and for the other 6 hours we would set the range to be 90 to 95% (which is what we currently use as standard on the unit). Some babies will start off at the higher range; some will start at the lower range. This will be decided by chance. After the 12 hours is complete, we will remove the transcutaneous monitor and your baby will be cared for in exactly the same way as is standard on the neonatal unit with an oxygen target range of 90-95%. So, in total, your baby would be targeted to a slightly higher oxygen level of 92-97% for only 6 hours.

Are there any risks, benefits or side effects for my baby?

We believe that there are no disadvantages for your baby in taking part in this study. Babies will only be targeted to a slightly higher oxygen level for a brief period. Previous studies measuring health outcomes have been carried out over many weeks. This study will not directly benefit your baby but we hope that the information we gather will allow us to better care for premature babies in the future.

Will my taking part in this study be kept confidential?

Yes. If you agree to take part, we will collect some details about your baby such as their gestation when they were born, their gender, and their weight at birth. During the study itself, the data we collect about oxygen levels will be completely anonymous. We will not store any information when the study is complete that could identify you or your baby.

What will happen to the results of the research study?

At the end of this study, the results will be analysed and we hope will be published in a medical journal. You and your baby will not be identified in any report or publication about the study.

Who has reviewed the study?

All research that involves NHS patients has been approved by an NHS Research Ethics Committee before it goes ahead. Approval means that the Committee is satisfied that your rights will be respected, that any risks have been reduced to a minimum and balances against possible benefits, and that you have been given sufficient information on which to make an informed decision to take part or not.

What do I do now?

If you'd like more information about the study, please let the research team member giving you this leaflet know. If you are happy to take part, we will ask you to sign a consent form. If at any time after signing the consent form you change your mind, you can withdraw from the study and we will delete any data from your baby if you want us to.

If you do not want to take part in the study – and there is no obligation – then you don't need to do anything further. No aspect of your baby's care will be affected by you not wanting to participate in the study.

Monitor – Parental Information Leaflet
Version 2 – 27 Nov 2017
194632

Contact details:

Contact from research team:

Dr Rod Kelly
Clinical / Research Fellow
Neonatal Transport Office, Royal Infirmary of Edinburgh
51 Little France Crescent, Edinburgh, EH16 4SA
Tel: 0131 242 2673
Email: rod.kelly@nhslothian.scot.nhs.uk

Independent contact from neonatal unit:

Dr. Judith Orme
Consultant Neonatologist
Neonatal Unit, Royal Infirmary of Edinburgh
51 Little France Crescent, Edinburgh, EH16 4SA
Tel: 0131 242 2601
Email: judith.orme@nhslothian.scot.nhs.uk

Complaints / Feedback contact:

Patient Experience Team
NHS Lothian, 2nd Floor Waverley Gate
2-4 Waterloo Place, Edinburgh, EH1 3EG
Tel: 0131 536 3370
Email:feedback@nhslothian.scot.nhs.uk

Participant ID:	

CONSENT FORM

MONITOR – Measuring Oxygenation of Newborn Infants in Targeted Oxygen Ranges

Please **initial** box

1. I confirm that I have read and understand the information sheet (DD MMM YYYY and Version Number) for the above study. I have had the opportunity to consider the information, ask questions and have had these questions answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw my baby at any time without giving any reason and without my baby's medical care and/or legal rights being affected. ☐
3. I give permission for the research team to access my baby's medical records for the purposes of this research study ☐
4. I understand that relevant sections of my baby's medical notes and data collected during the study may be looked at by individuals from the Sponsor (University of Edinburgh and/or NHS Lothian), from the NHS organisation or other regulatory authorities where it is relevant to my baby taking part in this research. I give permission for these individuals to have access to my baby's data and/or medical records. ☐
5. I give permission for my baby's personal information (including name, date of birth, consent form and contact details of individual with parental responsibility) to be passed to the University of Edinburgh and/or Trials Unit Centre for administration of the study ☐
6. (If appropriate) I give permission for my Community Health Index (CHI) number/hospital number to be collected and passed to the University of Edinburgh and/or Trials Unit Centre [NAME] ☐
7. I agree to my baby's anonymised data being used in future studies Yes ☐ No ☐
8. I confirm that I have 'parental responsibility for my baby' ☐
9. I agree for my baby to take part in the above study ☐

Name of Person Giving Consent	Date	Signature

Name of Person Receiving Consent	Date	Signature