ToSCiN

Timing of Stoma Closure in Neonates (ToSCiN)

Parent Information Sheet

We are doing research to help us understand when the best time is to close (reverse) a baby's stoma with a second operation and would like your help with this please.

Key Points

- We would like to talk to the parents of babies who have had a stoma and find out their views.
- If you would like to help, we would like to ask you some questions on the telephone or via an online platform: this will take around 45 minutes and take place once.
- Any information we record will be treated confidentially and anonymised.
- Taking part is completely optional and you can change your mind at any time.
- The results of this study will help us plan research in the future called a clinical trial.

Why are we doing this study?

Some babies require emergency surgery because they were born prematurely and developed a bowel problem like Necrotising Enterocolitis (NEC), or because they were born with a bowel blockage. As part of this surgery, a stoma may be needed. A stoma is where ends of the bowel are brought out to allow the baby to poo into a bag. Although a stoma can be life-saving, it can cause problems like dehydration, poor growth and skin problems. Because of this, reversing or 'closing' the stoma with a second operation is important and can affect: (i) when the baby can feed with milk; (ii) their growth; (iii) when they go home. We don't know the best time to close a stoma and because of this it varies between hospitals and between surgeons. We want to find out which time is best and to do this we need to do a type of research study called a clinical trial. Before a clinical trial is done it is important to find out current practice and whether a trial is acceptable to parents and doctors. This study (ToSCiN) will do this.

The ToSCIN study will take place in neonatal units across the UK. We will collect information about babies who recently had a stoma to find out what influences the decision of when to close it. We will also talk to parents and doctors to find out what they think about a future trial. We will use this information to decide if it would be possible to run a trial in the future. If it is, we will use the information to design a trial that is acceptable to parents and doctors, includes the most appropriate babies, and measures things important to parents and doctors.

We have asked you to be involved as we are looking to include the parents of babies who have had a stoma formed in the past, by talking to them and asking their views.

What does this study involve?

We would like to interview about 25 parents whose baby has had a stoma to find out what they think about a future research trial and how it should be done. If you would like to be involved in the study, we would arrange an interview where you could talk to one of our researchers.

What will happen if I wish to take part in an interview?

Before the interview, we will send you a short information sheet (like this one) – this will be a draft example of one that might be used to invite parents to take part in a future trial. During the interview, we will ask you what you think about the information sheet and how we can make it better. We will also ask about the best way to speak to parents about this proposed trial. With your permission we would like to record the interview. The interview should take about 45 minutes and can be done over the telephone or via an online platform (e.g. Zoom). After the interview, we will send you a £30 Amazon voucher to thank you for your time. We will send the recording of the interview to a transcription company who will write up what has been said. The recording will be stored safely and securely with the appropriate confidentiality agreements in place. The write-up of the interview will then have all identifying details (such as names) removed, and the original recording will be deleted.

If you have any questions please talk to the research team whose details are at the bottom of this page.

What if the interview is distressing?

If you become distressed during the interview, the researcher will immediately suspend the interview and stop recording. You and the researcher will decide together whether the interview can continue. If you feel unable to continue, the researcher will offer to contact a family member or friend, and will also direct you to relevant support services, for instance, the charity Bliss (***hello@bliss.co.uk*** or telephone: 020 7378 1122), who are supporting this research project. The researcher will not leave you in a distressed state.

What will happen to the results of the research study?

At the end of the study the results will be published in a medical journal. They will also be available on the trial website: ***www.npeu.ox.ac.uk/toscin***. You and your child will not be identified in any report or publication about the study.

Who is organising and funding the research?

The study is being managed by the Manchester University NHS Foundation Trust (Sponsor). The National Perinatal Epidemiology Unit Clinical Trials Unit at the University of Oxford is coordinating the study administration. Researchers at the University of Liverpool are coordinating and performing the interviews. The study is funded by The National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme.

Who has reviewed the study?

All research in the NHS is assessed by an independent group of people to protect the interests of the people taking part in it. This study has been reviewed by the London - Dulwich Research Ethics Committee.

What if I want to withdraw myself from the study?

If you decide that you no longer want to participate in an interview, please contact Dr Kerry Woolfall using the details at the end of this leaflet. You do not have to give a reason for withdrawing.

What if something goes wrong?

It is extremely unlikely that anything will go wrong. If at any stage you have any concerns about this study or the way it has been carried out, you can contact the people listed below. The normal National Health Service complaints mechanisms are also available to you. For NHS service advice or support please contact Patient Advice and Liaison Services (PALS) services. The charity Bliss can also provide a wide range of free services for the families of premature and sick babies, including emotional and practical support. They are supporting this research project and can be contacted via email: ***hello@bliss.co.uk*** or telephone: 020 7378 1122.

What will happen to the information?

In this research study we will collect some personal information about you including name and contact details. This information will be held by the ToSCiN study team at the University of Liverpool.

We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study.

Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.

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How to contact us

Principal Investigator	Interview Team	Patient Advice and Liaison Services (PALS)
{_LEAD_}	Dr Kerry Woolfall Tel: 0151 794 4634 K.Woolfall@liverpool.ac.uk	{_PALS_}

ToSCiN Study Team

NPEU Clinical Trials Unit, University of Oxford,
Old Road Campus, Headington, Oxford, OX3 7LF.

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Participant Information Sheet (Clinicians)

You are being invited to take part in a research study. Please ask us if there is anything that is not clear in this information sheet or if you would like more information (contact details overleaf).

Key Points

- The timing of neonatal stoma closure is variable around the UK and the best time remains unclear. Ideally, a clinical trial to compare early and late closure would be conducted but this is likely to be challenging and needs to be feasible and acceptable to parents and clinicians.
- ToSCiN aims to answer the question, "Is it feasible to conduct a clinical trial comparing 'early' vs 'late' stoma closure in neonates?"
- We would like to gather the viewpoints of clinicians to (i) help us describe current UK practice; (ii) establish whether or not a clinical trial (and exactly what form of trial) is acceptable; and (iii) establish the design of a potential trial, including defining the intervention ('early' vs. 'late') and the population of infants to be included, how infants should be recruited and what information should be collected (outcomes).
- We would like to invite you to take part in an online focus group or interview to explore your views on the design and conduct of the proposed ToSCiN trial.
- Any information we record will be treated confidentially and anonymised.
- Taking part is completely optional and you can change your mind at any time, without affecting your legal rights or working relationships/career.
- The results of this study will help us plan research in the future called a clinical trial.

Why have I been chosen?

As you are involved in the care of infants requiring emergency stoma closure, your views are very important to us. We aim to involve surgeons, neonatologists, specialist nurses and dieticians from across participating sites.

What will happen if I take part?

We will ask you to register interest in taking part in either a focus group or a telephone interview. Focus groups will take place online (via Microsoft Teams or Zoom) and interviews will take place via telephone or online. Each focus group will take about 60-90 minutes and involve 8-10 people. Individual interviews will be arranged for up to 10 clinicians who register interest in taking part, but are unable to attend a focus group. Telephone interviews will take about 40-60 minutes. With your permission, focus groups and interviews will be recorded and transcribed by a third-party company with whom a confidentiality agreement is in place. The transcriptions will be anonymised and the original recordings will be deleted after this.

All interviews and focus groups will be conducted by the University of Liverpool ToSCiN study team.

What are the possible benefits and risks of taking part?

This qualitative element of the study is very low risk. Should you want to discuss any aspect of the study, please contact Kerry Woolfall (details below).

Findings of this study will be used to inform the design of a future clinical trial. We cannot promise that you or the families you work with will benefit directly from this study, but many people find that taking part in studies of this sort is useful because they have a chance to air their views and to reflect on things.

Who is involved in the study?

Your surgical unit is one of the units taking part in this study. The study is being run by the Manchester University NHS Foundation Trust (Sponsor). The National Perinatal Epidemiology Unit Clinical Trials Unit at the University of Oxford is coordinating the study administration. Researchers at the University of Liverpool are coordinating and performing

the interviews. The National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme is funding the study. Mr Nick Lansdale (Royal Manchester Children's Hospital) is the ToSCiN Study Chief Investigator. Parents of children who have experienced stoma closure have been involved in the development of this study.

Who has reviewed the study?

All research in the NHS is assessed by an independent group of people to protect the interests of the people taking part in it. This study has been reviewed by the London - Dulwich Research Ethics Committee.

What if something goes wrong?

Any complaint about the conduct of this study, the way you have been dealt with during the study or any possible harm you might suffer will be addressed. If you have a concern about any aspect of this study, then you should speak to the researchers who will do their best to answer your questions (see contact details below). If you remain unhappy and wish to complain formally, then you can do this through the NHS Complaints Procedure. Details can be obtained from your employer.

What if I want to withdraw myself from the study?

If you decide that you no longer want to participate in an interview or focus group, please contact Dr Kerry Woolfall using the details at the end of this leaflet. You do not have to give a reason for withdrawing and can withdraw without affecting your legal rights or working relationships/career.

What will happen to the information?

All information that we collect about you during the study will be kept strictly confidential and stored securely. If you decide to take part, we will collect some personal information about you including name and contact details. This information will be held by the ToSCiN study team at the University of Liverpool. It will only be accessed by the ToSCiN study team. For more information on how we process and protect your data, please contact the interview team.

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