Participant Information Sheet

Interventional Study - *Parent/Guardian consenting on behalf of participant*

Title	SURFactant Administration by SUPraglottic Airway
Short Title	The SURFSUP Trial
Protocol Number	Version 2.0, 17/07/2023
UK Appendix protocol	Version 3.0, 24/02/2025
Coordinating Principal Investigator/ Principal Investigator	Dr Calum Roberts
Associate Investigator(s)	Dr Joyce O'Shea
Location	Royal Hospital for Children Glasgow

Part 1 What does my baby's participation involve?

1 Introduction

This is an invitation for your baby to take part in this research project because they are premature and need surfactant treatment. The research project is comparing two different ways to give surfactant to premature babies.

This Participant Information Sheet tells you about the research project. It explains the treatments involved. Knowing what is involved will help you decide if you want your baby to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not your baby can take part, you might want to talk about it with a relative, friend or your baby's local doctor.

Participation in this research is voluntary. If you do not wish your baby to take part, they do not have to. Your baby will receive the best possible care whether or not they take part.

If you decide you want your baby to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:
• Understand what you have read
• Consent to your baby taking part in the research project
• Consent for your baby to have the treatments that are described
• Consent to the use of your baby's personal and health information as described.

You will be given a copy of this Participant Information to keep.

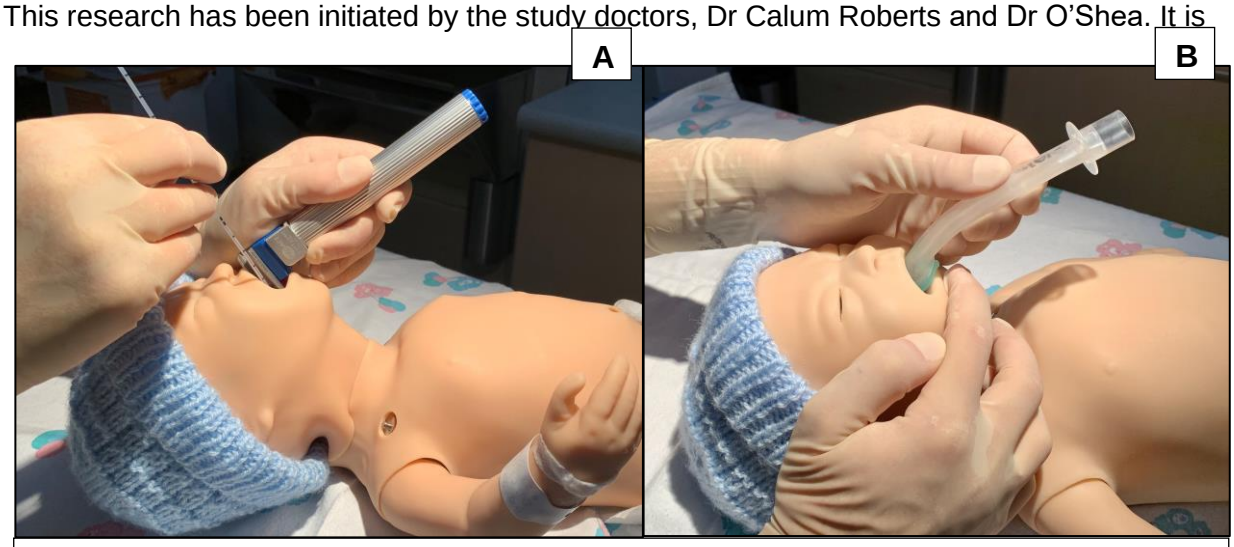
2 What is the purpose of this research?

Babies who are born prematurely (before 37 weeks of pregnancy) have immature lungs and may need breathing support for a condition called respiratory distress syndrome (RDS). Some babies will require treatment with surfactant, a liquid medicine that is given into the lungs to help them to breathe more effectively. The research project is comparing two different ways to give surfactant to babies that need it. Both of these methods are currently used at the Children's Hospital in Glasgow. We don't know which method is better.

The current most common method to give surfactant treatment is for the treating doctor to look into the baby's mouth using a device called a laryngoscope, and to place a catheter (thin plastic tube) into the airway through which the surfactant is given into the lungs (**Picture A**).

A different newer way to give the surfactant treatment is with a supraglottic airway, a flexible plastic tube that can be placed in the baby's airway by a doctor without using a laryngoscope (**Picture B).** Supraglottic airways are frequently used as a method of providing breathing support for babies at birth, and more recently are being used to give surfactant. Supraglottic airways are easier to place than a tube in the airway, so it may be possible to provide surfactant treatment with fewer attempts and less risk than with a laryngoscope and catheter. Previous research, about 350 babies in total, suggests that supraglottic airways can be successfully used to give surfactant treatment, but a larger study is needed before we know whether this should become standard treatment. This research project aims to find out if the newer method, supraglottic airway surfactant treatment, is as effective as the standard method of using a laryngoscope and catheter.

This research has been initiated by the study doctors, Dr Calum Roberts and Dr O'Shea. It is being conducted at in hospitals in Australia and Europe.



A: Laryngoscope and catheter (standard method)

B: Supraglottic airway (newer method)

3 What does participation in this research involve?

Your baby will be participating in a study called a randomised controlled trial. This is because we do not know which method is better for giving surfactant treatment to babies. We will put the babies into two groups and compare the results to see if one is better: one group of babies will receive surfactant by laryngoscope and catheter, and the other group of babies will receive surfactant by supraglottic airway. To try to make sure the groups are the same, each baby is put into a group by chance (random), so there is an equal chance (like flipping a coin) for your baby to receive either treatment method.

Other than the method of surfactant treatment, the treatment provided to babies in the research project will not be any different to standard care, and no extra tests are required. We will record health information from your baby's medical records up until they are discharged home. We will also take a video recording of your baby receiving surfactant treatment to collect information about the two treatment methods.

If you provide consent for us to do so, a member of the SURFSUP team will contact you by phone and ask you to complete a survey about your baby's health and wellbeing when they are two years old.

There are no additional costs associated with participation in this research project, nor will you be paid. All medical care required as part of the research project will be provided to your baby free of charge.

4 Does my baby have to take part in this research project?

Participation in any research project is voluntary. If you do not wish for your baby to take part, they do not have to. If you decide that they can take part and later change your mind, you are free to withdraw your baby from the project at any stage. If you do decide that your baby can take part, you will be given this Participant Information and a Consent Form to sign and you will be given a copy of both to keep.

Your decision that your baby can or cannot take part, or that they can take part and then be withdrawn, will not affect their routine treatment, relationship with those treating them, or their relationship with the Royal Hospital for Children in Glasgow.

5 What are the alternatives to participation?

If you choose for your baby not to take part in this research project, they will receive surfactant treatment by method preferred by the treating clinician. No research information will be collected.

6 What are the possible benefits of taking part?

We cannot guarantee or promise that your baby will receive any benefits from this research. The results of this research project may help us learn how best to give surfactant treatment to other babies in the future.

7 What are the possible risks and disadvantages of taking part?

Treatment with surfactant can have side effects for some babies, which include a temporary reduction in oxygen levels or heart rate. We do not know if these side effects will occur at a similar rate in both groups, or more commonly in one group than the other. If the staff looking after your baby need to stop or pause surfactant treatment for any reason, they will do so.

8 What happens when the research project ends?

When the research project ends, information about the results will be made available to parents on the Monash Newborn website: https://monashchildrenshospital.org/monash-newborn/

Part 2 How is the research project being conducted?

9 What will happen to information about my baby?

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about your baby for the research project and videorecording your baby while they get surfactant. Any information obtained in connection with this research project that can identify your baby will remain confidential. Your baby's information including the videorecording will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.
Information about your baby may be obtained from their paper or electronic notes held at this and other health services, for the purpose of this research. By signing the consent form, you agree to the study team accessing health records if they are relevant to your baby's participation in this research project. Information about your baby's participation in this research project may be recorded in their health records.

We expect that this research project will be published and or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that your baby cannot be identified, except with your permission.

If your baby is enrolled, some parts of your baby's medical records and data collected specifically for the study may be examined by authorised persons from the organisation sponsoring the research. Collected data may be examined by authorised people to check that the study is being conducted appropriately and we will do our best to meet this duty. Personal information will be kept confidential and stored securely. The videorecording of your baby being treated will be stored securely. All information sourced from your baby will be kept confidential, and only be disclosed with your permission or if required by law. Only people involved in the study will have access to the trial data. Study data will be stored at the hospital for at least 15 years. Participants will not be identified in any publication.
With your consent, the discharge summary letter of your child's care sent to your GP will include that your baby is involved in the study.

All study staff have up-to-date Good Clinical Practice certification and comply with the requirements of the Data Protection Act 2018 and the General Data Protection Regulations 2018, regarding collection, storage, processing and disclosure of personal information and will uphold the Act's core principles.
NHS Greater Glasgow and Clyde is the UK lead of this study sponsored by Monash Health in Australia. We will be using information from your baby and your baby medical records in order to undertake this study and will act as the data processor for this study.
Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained.
You can find out more about how we use your information at
https://www.hra.nhs.uk/information-about-patients or by contacting Dr Joyce O'Shea.

10 Complaints and Compensation

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions - please raise your concerns in the first instance with Dr Joyce O'Shea, her contact details are – joyce.o'shea@ggc.scot.nhs.uk, or telephone 0141 201 2297. If you remain unhappy and wish to complain formally, you can do this via the Patient Advice and Support Service (PASS). You can contact PASS by: visiting the PASS website at www.patientadvicescotland.org.uk and use webchat or by phoning the PASS national helpline 0800 917 2127. In the event that something does go wrong and you or your baby are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against the NHS. The normal National Health Service complaints mechanisms are available if you wish to complain or have any concerns (Tel: 0141 201 4500, Email: complaints@ggc.scot.nhs.uk).

11 Who has reviewed the research project?

All research in the NHS is examined by an independent group, called a Research Ethics Committee (REC), to protect your interests.

12 Further information and who to contact

The person you may need to contact will depend on the nature of your query.
If you want any further information concerning this project you can contact any of the following people:

Clinical contact person

Name	Dr Calum Roberts	Dr Joyce O'Shea
Position	Consultant Neonatologist	Consultant Neonatologist
Email	Calum.roberts@monashhealth.org	joyce.o'shea@ggc.scot.nhs.uk