

SurfON: Surfactant or not for babies born early with breathing problems

Submission date 10/02/2020	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 20/02/2020	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 07/05/2025	Condition category Neonatal Diseases	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

This study is about babies born two to six weeks before their due date. Babies born even a few weeks early are not fully developed. These babies may have breathing problems after birth, which can be severe. Some need to go onto a breathing machine (ventilator) soon after birth; others do not, but still need some help with breathing. They often go onto 'non-invasive' breathing support, which means that machines give oxygen through soft, short tubes in the nose or small masks over the nose.

The lungs of healthy full term babies produce surfactant, a substance that makes it easier for them to breathe. Babies born early often do not make enough surfactant, or their natural surfactant does not work properly. The researchers can give a dose of surfactant into the lungs- down a small tube in the windpipe and many of the most premature babies are given it routinely. In babies born closer to term it is harder to predict who will need surfactant and who will get better without it.

There have been no research studies in babies born two to six weeks early with breathing problems. The researchers want to know if it is better to give surfactant early, when a baby first starts to need help with breathing, or wait to see if they improve without it.

Who can participate?

Babies born at 34+0 – 38+6 weeks of gestation, with respiratory distress.

What does the study involve?

Infants born 2-6 weeks early needing non-invasive respiratory support will be randomly allocated to receive either early surfactant therapy or expectant management. Infants allocated to the early surfactant therapy will receive a single dose of surfactant. For those infants allocated to the other arm, doctors will wait to see how their breathing responds to standard care. Infants in either arms may receive an additional dose of surfactant later on, if the doctor feels it is necessary.

The researchers will collect some information such as duration of stay in hospital, duration of non-invasive support, breast milk feeding etc about the mother and infant from medical records. The mother will be asked to fill in a short questionnaire after they provide consent and

just before their infant leaves the hospital. The researchers will also keep a record of any hospital visits the infant has in their first year through routine NHS data.

What are the possible benefits and risks of participating?

Whilst there may not be any direct benefit in taking part in the study, your participation will be invaluable to help improve future care for these babies. Surfactant is routinely used in babies and there are no extra risks involved from taking part in the study.

Where is the study run from?

NPEU CTU, University of Oxford (UK)

When is the study starting and how long is it expected to run for?

June 2019 to August 2025

Who is funding the study?

National Institute for Health Research (NIHR) Health Technology Assessment (HTA) Programme (17/89/07) (UK)

Who is the main contact?

SurfON trial team

surfion@npeu.ox.ac.uk

Study website

<https://www.npeu.ox.ac.uk/surfion>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

2019-003764-45

IRAS number

269023

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

CPMS 44406, IRAS 269023

Study information

Scientific Title

Multicentre, open-label, randomised controlled trial of early surfactant therapy versus expectant management in late preterm and early term infants with respiratory distress

Acronym

SurfON

Study objectives

The aim is to investigate whether, in late preterm and early term infants with respiratory distress, the early use of surfactant versus expectant management, results in a shorter duration of hospital stay and fewer infants who fail to respond to treatment.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 14/02/2020, East Midlands - Derby Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 1048098; NRESCCommittee.EastMidlands-Derby@nhs.net), ref: 20/EM/0003

Study design

Interventional randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Respiratory and cardiovascular disorders specific to the perinatal period

Interventions

This is a randomised controlled trial. Infants born 2-6 weeks early needing non-invasive respiratory support will be randomly allocated to receive either early surfactant therapy or expectant management. Infants allocated to the early surfactant therapy will receive a single dose of surfactant. For those infants allocated to the other arm, doctors will wait to see how their breathing responds to standard care. Infants in either arms may receive an additional dose of surfactant later on, if the doctor feels it is necessary.

The researchers will collect some information such as duration of stay in hospital, duration of non-invasive support, breast milk feeding etc about the mother and infant their from medical records. The mother will be asked to fill in a short questionnaire after they provide consent and just before their infant leaves the hospital. The researchers will also keep a record of any hospital visits the infant has in their first year through routine NHS data.

Intervention Type

Procedure/Surgery

Primary outcome measure

1. Length of infant's hospital stay after birth, defined as the number of days from birth to discharge home from hospital
2. Incidence of severe respiratory failure, defined as, sustained (≥ 30 minutes) requirement for $\text{FiO}_2 \geq 0.45$ to maintain oxygen saturations (SaO_2) $\geq 92\%$, between trial entry and discharge home from hospital

Secondary outcome measures

Perinatal clinical outcomes measures:

1. Total duration of NNU stay, defined as total number of days of inpatient care in a neonatal unit (defined according to Healthcare Resource Group (HRG) Critical Care categories 1–5, 2016)
2. Total duration of neonatal intensive care, defined as number of days of neonatal intensive care (defined according to HRG Critical Care categories 1–5, 2016)
3. Duration of mechanical ventilation, defined as days of ventilation via an ETT
4. Duration of non-invasive respiratory support, using positive airway pressure or high flow
5. Pulmonary air leaks, requiring insertion of a chest drain
6. Days of mother-infant separation, defined using HRG Critical Care categories 1–5, 2016
7. Breast milk feeding, defined as (a) any breast milk feeding during neonatal hospital stay, (b) any breast milk feeding at hospital discharge and (c) exclusive breast milk feeding at hospital discharge
8. Late onset sepsis, defined as the incidence of microbiologically-confirmed or clinically suspected invasive infection more than 72 hours after birth
9. Need for inhaled nitric oxide (iNO) therapy
10. Need for Extra-corporeal membrane oxygenation (ECMO)
11. Medical respiratory diagnoses, defined as any respiratory diagnosis attributed to the infant
12. Surfactant administration, defined as (a) administration of any additional surfactant in infants randomised to receive early surfactant or (b) administration of any surfactant in infants receiving expectant management, including number of doses and dose given
13. Maternal length of hospitalisation, defined as the total number of days spent by the mother in hospital after trial entry

Health economics outcomes measures:

14. Cost of maternal hospitalisation
15. Self-reported maternal health-related quality of life
16. Costs associated with neonatal care
17. Paediatric secondary care use and associated costs using routine national databases such as Hospital Episode Statistics (HES) data

Overall study start date

01/06/2019

Completion date

31/08/2025

Eligibility

Key inclusion criteria

1. Born at 34+0–38+6 weeks of gestation
2. ≤ 24 hours old
3. Respiratory distress defined as:
 - 3.1. $\text{FiO}_2 \geq 0.3$ and < 0.45 needed to maintain $\text{SaO}_2 \geq 92\%$, or
 - 3.2. Clinically significant work of breathing, regardless of FiO_2
4. Clinical decision to provide non-invasive respiratory support
5. Written parental informed consent

Participant type(s)

Patient

Age group

Neonate

Upper age limit

1 Days

Sex

Both

Target number of participants

Planned Sample Size: 1,522; UK Sample Size: 1,522

Total final enrolment

1515

Key exclusion criteria

1. Major structural or chromosomal abnormality
2. No realistic prospect of survival
3. Prior intubation and/or surfactant administration
4. Known or suspected hypoxic ischaemic encephalopathy
5. Congenital abnormality of the upper or lower respiratory tract
6. Known or suspected neuromuscular disorder

Date of first enrolment

03/09/2020

Date of final enrolment

30/04/2025

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Leicester Royal Infirmary

University Hospitals Of Leicester NHS Trust

Infirmary Square

Leicester

United Kingdom

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Sponsor information

Organisation

University of Leicester

Sponsor details

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Sponsor type

University/education

Website

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ROR

<https://ror.org/04h699437>

Funder(s)

Funder type

Government

Funder Name

Health Technology Assessment Programme; Grant Codes 17/89/07

Alternative Name(s)

NIHR Health Technology Assessment Programme, HTA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Funder Name

National Institute for Health Research (NIHR) (UK)

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

30/06/2025

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No