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

Submission date	**Recruitment status**	[X] Prospectively registered
10/02/2020	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/02/2020	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
02/12/2025	Neonatal Diseases	[X] 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 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.

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
surfon@npeu.ox.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Elaine M. Boyle

Contact details
Department of Health Sciences
College of Life Sciences
George Davies Centre
University of Leicester
University Road
Leicester
United Kingdom
LE1 7RH
+44 (0)116 252 5447
eb124@le.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
2019-003764-45

Integrated Research Application System (IRAS)
269023

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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; NRESCommittee.EastMidlands-Derby@nhs.net), ref: 20/EM/0003

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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(s)
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 FiO2 ≥ 0.45 to maintain oxygen saturations (SaO2) ≥ 92%, between trial entry and discharge home from hospital

Key secondary outcome(s))
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

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. FiO2 ≥ 0.3 and < 0.45 needed to maintain SaO2 ≥92%, or
3.2. Clinically significant work of breathing, regardless of FiO2
4. Clinical decision to provide non-invasive respiratory support
5. Written parental informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Lower age limit
0 days

Upper age limit
1 days

Sex
All

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
United Kingdom

England

Study participating centre
Leicester Royal Infirmary
University Hospitals Of Leicester NHS Trust
Infirmary Square
Leicester
England
LE1 5WW

Sponsor information

Organisation
University of Leicester

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, Health Technology Assessment (HTA), 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

Individual participant data (IPD) sharing plan

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?
Protocol article		01/12/2025	02/12/2025	Yes	No
HRA research summary			28/06/2023	No	No
Study website		11/11/2025	11/11/2025	No	Yes