SurfON
Surfactant Or Not

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UNIVERSITY OF LEICESTER

NPEU Clinical Trials Unit

OXFORD POPULATION HEALTH
UNIVERSITY OF OXFORD
NPEU

Zachary Nathan Phillips, with kind permission from his parents.

SurfON Study

Screening and Eligibility Bite size session

8th of May 2024

Study Design & Summary

- Study Design

Multicentre, open-label, randomised controlled trial

- Study Arms

Expectant management

Early surfactant therapy

- Sample Size

1,522 infants across UK in NICUs and LNUs.

SCUs are also now included following Substantial Amendment 07 approval

- Recruitment period

Recruitment will continue until the end of February 2025.

- Follow up

Remote FU with no direct contact with participants at one year of age, corrected for prematurity

- Team

Study Coordinating centre – NPEU CTU, University of Oxford

Sponsor – University of Leicester

Funder – NIHR HTA Programme

HYPOTHESIS

Early, proactive management of respiratory disease will

- reduce the progression to severe respiratory failure requiring mechanical ventilation
- reduce length of hospital stay
- reduce early hospital readmissions
- reduce costs of neonatal care

Current practice

- Variable between and within neonatal units
- Some clinicians treat early with surfactant to prevent deterioration
- Some prefer to adopt a ‘watch and wait’ approach
- No defined limits for intervention
- No evidence for either approach
- Both can be regarded as “standard care”
- No RCTs in this group of babies

Screening and Eligibility Criteria

Study Criteria
Protocol Version 6.0

Inclusion criteria

1. Born at 34^{+0}–38^{+6} weeks of gestation
2. ≤ 24 hours old
3. Respiratory distress, defined as:
   - FiO_2 ≥ 0.3 and < 0.45 to maintain oxygen saturations SaO_2 ≥ 92%

   or

   - Clinically significant work of breathing, regardless of FiO_2
4. Clinical decision to provide non-invasive respiratory support
5. Written parental informed consent

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 respiratory tract
6. Known or suspected neuromuscular disorder

Study Criteria
Protocol Version 7.0

Inclusion criteria

1. Born at 34^{+0}–38^{+6} weeks of gestation
2. ≤ 24 hours old
3. Respiratory distress, defined as:
   - FiO_2 ≥ 0.3 and < 0.45 to maintain oxygen saturations SaO_2 ≥ 92%

   or

   - FiO2 <0.3 **with** clinically significant work of breathing
4. Clinical decision to provide non-invasive respiratory support
5. Written parental informed consent

Exclusion criteria

1. Major structural or chromosomal abnormality
2. No realistic prospect of survival
3. Prior intubation and/or surfactant administration
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RECRUITMENT Hints and Tips

SurfON

Early Approach is Key!

Times when it may be appropriate to **approach** parents about SurfON

- If you are admitting a baby who meets the gestation criteria because they are exhibiting signs of respiratory distress, regardless of a need for respiratory intervention at this point
- If you are counselling a mother whose baby is being delivered late preterm or early term and there is suspicion the infant may need neonatal unit admission

Times when it may be appropriate to approach and **consent, but not randomise** to SurfON

- If the baby has an oxygen requirement, regardless of a decision to commence non-invasive respiratory support
- If the infant is on ncpap or high flow, but is in less than 30% oxygen and does not have clinically significant work of breathing

Times when it is appropriate to **consent and randomise** to SurfON

- If the infant is on ncpap or highflow and has significant work of breathing, regardless of oxygen requirement
- If the infant meets the entry criteria, but enrolment may mean the infant could subsequently need transferring out

Screening & Eligibility Checks

- ✓ Aim to approach parents early after infant's admission, when respiratory distress occurs (*can be before inclusion criteria reached*)

- ✓ Women expected to deliver at 34-36 weeks may be made aware of the study prior to delivery, at the clinical team's discretion. Liaise with maternity unit staff to make sure that they are familiar with the study

- ✓ Please include all pregnant women or infants screened in the **Screening Log**, even if they decline participation (avoid duplications!)

- ✓ Screening can be completed by any trained staff member

- ✓ However, eligibility will be reconfirmed at the point of consent & randomisation by *delegated medically trained doctor & ANNPs*
- ✓ Where parents do not have a good understanding of English, sites may use the translation and interpreting services, which they routinely use in clinical practice to communicate about the trial.

Screening and Logs

Once a month, upload summary data for those screened on the SurfON randomisation (https://rct.npeu.ox.ac.uk/surfon/login.php)

Screening log tips c/o Helen Harizaj from Medway NHS Foundation

'We have looked at our screening logs and seen that we had 38 patients incorrectly documented as ineligible, all of these patients were on VT so all of them could have been approached and consented, whether or not they were eligible for randomisation would have depended on their level of WOB.'

Site Success

- Delegate team; strong delegate team with lots of enthusiastic trainees
- Certificate and gift for the highest recruiter every month
- Awareness raised at departmental monthly research meetings; opportunity for the PI to provide education, answer questions and encourage more participation
- Research nurse and PI attend daily handovers and safety briefings to hear about potential participants so we approach as soon as possible.
- Delegates and the neonatal team encouraged to approach early as soon as an eligible participant is admitted to offer the patient information leaflet and a delegate will return to have a chat and obtain informed consent.
- PI always available on the phone to answer delegate questions and confirm eligibility of potential participants.

With thanks to Doris Iyamabo, Principal Investigator, Luton and Dunstable Hospital

Challenges

- Attending Clinician interpretation on eligibility criteria
- The PI and delegate use opportunities when there may be queries to discuss with the attending clinician and team.
- Missed opportunities to recruit if no delegate available.

Site Experiences and any Questions?

SurfON Bite Size Training Sessions

Please see the schedule of planned virtual training sessions, which follow the participant journey.

Each session be approximately will be 30 minutes long with a further 15 minutes for any question, or an opportunity for sites to share their experiences.

Topic	Date	Time	Duration
Drop in Session	17/04/2024	12.00pm	30 minutes
Screening and Eligibility	08/05/2024	12.00pm	45 minutes
Drop-in session	06/06/2024	11.30am	30 minutes
Consent and Incident Forms	10/07/2024	11.30am	45 minutes
Drop-in Session	07/08/2024	11.30am	30 minutes
Data Queries	05/09/2024	11.30am	45 minutes
Drop-in Session	03/10/2024	11.30am	30 minutes

Thank you for listening

SurfON Study Team

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

P: 01865 289437
E: surfon@npeu.ox.ac.uk
W: www.npeu.ox.ac.uk/surfon

- Training podcasts and further resources for use at internal training events, grand rounds etc:
- https://www.npeu.ox.ac.uk/surfon/clinicians/podcasts
- https://www.npeu.ox.ac.uk/surfon/clinicians/resources
- https://www.npeu.ox.ac.uk/surfon/clinicians/training-materials

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