

# Relaunching

# SURFON

## Surfactant Or Not

## Recruitment Restart

04 July 2022

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



- Inclusion criteria**
- 34<sup>+0</sup> – 38<sup>+6</sup> weeks gestation
  - ≤ 24 hours old
  - Respiratory distress
    - FiO<sub>2</sub> ≥ 0.3 and < 0.45 needed to maintain SaO<sub>2</sub> ≥ 92% OR
    - Clinically significant work of breathing, regardless of FiO<sub>2</sub>
  - Clinical decision to provide non-invasive respiratory support
  - Written parental informed consent

- Exclusion criteria**
- Major structural or chromosomal anomalies
  - No realistic prospect of survival
  - Prior intubation and/or surfactant administration
  - Known or suspected hypoxic ischaemic encephalopathy
  - Congenital abnormality of the upper or lower respiratory tract
  - Known or suspected neuromuscular disorder

Randomisation 1:1 allocation ratio

Early surfactant therapy

OR

Expectant management

- Primary Outcomes (from trial entry to hospital discharge home)**
- Length of infant's hospital stay after birth, defined as the number of days from birth to discharge home
  - Incidence of severe respiratory failure, defined as:
    - sustained (≥ 30 minutes) requirement for FiO<sub>2</sub> ≥ 0.45 to maintain oxygen saturations (SaO<sub>2</sub>) ≥ 92%

If you are interested in taking part as a site or for more info, please contact **SurfON Study Team.**

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For further details please refer to the study Protocol.

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