



# <u>SURF</u>actant Administration by <u>SUP</u>raglottic Airway (the SURFSUP Trial):

# **Randomisation Link** (however important to decide the clinician and

escalation clinician/s who will attempt procedure prior to randomising

How to randomise: See appendix 1 below

#### Things needed by study clinician:

- Where possible give PIL to parents and discuss study giving them a few minutes to consider if they wish to join.
- Take consent-this is one form, please leave in the locked draw with GoPro camera after the procedure
- Randomise the infant-log into RedCap-details above and below
- Undertake the procedure
- Fill in the paper the treatment information and clinician survey forms (or online version-requires logging back into RedCap)
- Leave GoPro camera, Parent info, consent and clinician forms in the locked draw-Surfon draw above death certificate draw-accessed via Nursing TL

#### Study summary:

Unblinded, multi-centre, randomised controlled trial to evaluate the effectiveness and safety of surfactant administration via supraglottic airway, compared with standard surfactant administration methods via laryngoscopy, in preterm infants with respiratory distress syndrome

## The Local Principal Investigator is David Quine-Any problems please contact me: Office number: 22577 Mobile:07728966304 (Whatsapp me and will phone back)

#### **Inclusion Criteria**

- Born preterm at <37 weeks' gestation
- Birth weight ≥1250 g
- Age <48 hours
- Diagnosis of RDS, confirmed with CXR or lung USS, except where surfactant treatment is required urgently and would be delayed by imaging
- FiO<sub>2</sub> ≥0.30 on non-invasive respiratory support (CPAP/NIPPV or nHF)

#### **Exclusion criteria**

- Previous treatment with surfactant or mechanical ventilation via ETT
- Urgent need for intubation and mechanical ventilation as per treating clinician
- Known pneumothorax
- Major congenital anomaly of lungs, heart, or airway
- Not receiving full active intensive care (i.e., palliative/comfort care)

If an eligible baby is identified then the parents should be approached for consent for their baby to be included in the study (has to be a staff member who has been allocated this responsibility on the study delegation log).

Parent information leaflets, consent and clinician forms are available in the study box at the staff base.

Full Protocol: See link on left if not working

LMA Technique:

GoPro procedure:

Parent info sheets:

### Appendix 1

### How to randomise and forms that need filling in:

1. Ensure parental consent is in place prior to randomizing (we are taking consent and then photocopying the form, ensure the consent form is left in the locked draw with the GoPro for the research nurse/doctors to sort this)

#### 2. Confirm eligibility of infant as below:

#### Eligibility

- Born preterm at <37 weeks' gestation
- Birth weight ≥1250 g
- Age <48 hours
- Diagnosis of RDS, confirmed with CXR or lung USS, except where surfactant treatment is required urgently and would be delayed by imaging
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#### Exclusions

- Previous treatment with surfactant or mechanical ventilation via ETT
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- Major congenital anomaly of lungs, heart, or airway
- Not receiving full active intensive care (i.e., palliative/comfort care)

# 3. Access REDCap website on a computer or smartphone:

- a. https://redcap.helix.monash.edu
- b. Press Blue button-login with SSO/OKTA

→ Login with SSO/OKTA

- c. Sign in as Monash Guest, you will need to register the first time.
- d. Select My Projects then SURFSUP 1 Trial
- e. Select Add/Edit Records, then click the + Add new record button
- f. Complete the study centre and weight details, and confirm eligibility

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Please confirm eligibility (all must apply) * must provide value				Preterm infant born at < 37 weeks' gestation Birth weight 1250g or greater Age < 48 hours at randomisation Diagnosis of RDS Fi02 0.30 or higher on non-invasive respiratory		
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Randomised treatmen	t group			A Randomize	1	

- g. Click Randomize
- h. Ensure the entered values are correct in the pop-up box, and confirm by clicking **Randomize** again
- i. The allocated treatment group is displayed. You can now close the window
- j. After performing the procedure please simply fill in the treatment information and clinician survey forms (this needs to be done while you remember the event as asks about how you felt about the procedure)-paper forms are available.
- k. Leave the rest for the researchers