



The study can only be undertaken by trained personnel, to obtain this you need to have signed the following forms:

- The Site delegation log
- Site training log
- A Training attestation form

**Randomisation** is by Opaque randomisation envelopes (in locked Polar draw in middle office) -we will only be using the blue envelopes (26-28 week infants)

Envelopes contain:

- A4-Randomisation Sheet-either Static or Dynamic PEEP
- 1 x Randomisation sticker
- Delivery Room Management Paper CRF
- Please also collect a local laminated twin side algorithm sheet and use appropriate side according to randomisation. (in locked Polar draw)

### Study summary:

The trial aims to establish whether the use of a high, dynamic PEEP strategy to support the lung during stabilisation at birth, compared with a static, standard PEEP strategy, increases the rate of survival without bronchopulmonary dysplasia (BPD) in extremely preterm infants born <29 weeks post-menstrual age (PMA).

## Inclusion Criteria

Each infant must meet all the following inclusion criteria to be enrolled in this study:

1. The infant is born between 23 weeks 0 days and 28 weeks 6 days PMA (by best obstetric estimate) -**We are only enrolling infants from 26+0 to 28+6 weeks gestation.**
2. Is planned to receive respiratory intervention (resuscitation) at birth with CPAP and/or positive pressure ventilation in the DR to support transition and/or respiratory failure related to prematurity
3. The infant has a parent or other legally acceptable representative capable of understanding the informed consent document and providing consent on the participant's behalf prospectively

## Exclusion Criteria

Infants meeting any of the following criteria will be excluded from the study:

1. The infant is not planned for active care based on assessment of the attending clinician or family decision
2. The infant has anticipated severe pulmonary hypoplasia due to rupture of membranes <22 weeks' with anhydramnios or fetal hydrops
3. The infant has a major congenital anomaly or anticipated alternative cause for respiratory failure
4. Refusal of informed consent by their legally acceptable representative
5. The infant does not have a guardian who can provide informed consent.

## Study Procedure:

- Where possible give PIL to parents and discuss study giving them a few minutes to consider if they wish to join. There is also a parent education video link (both PIL and consent forms are kept in the Polar Draw in the middle office)
- Take consent-this is one form, please leave in the locked draw after the procedure
- Randomise via taking the next numerical envelope from the locked Polar draw as above
- In the event of multiple births, select the next envelope in sequence and assign an envelope to each infant independently according to birth order
- Open the randomisation envelope
- The team member should loudly and clearly announce the randomisation group allocated
- All team members acknowledge the randomisation group (closed loop communication), identify, and confirm correct side of laminated trial algorithm to be used
- Undertake a team huddle (and delivery room pause) Review initial steps and timing for assessment(s) for the allocated static PEEP (control group) or dynamic PEEP (intervention group) algorithm, including placing a laminated version of the allocated algorithm within easy view of team.
- Address all questions and concerns by members of the DR team.
- Follow the appropriate algorithm and fill in Delivery Room Management Paper CRF

- After 20 mins or after stabilised and ready for transfer the PEEP can be moved back down to 5-6 cm.
- Ensure one of the local individuals is able to fill in Redcap database with the infants details within 24-48 hours (this will mean contacting either David, Sally, Frazer)

## **Intubation criteria first 72 hours:**

- After the 20 min intervention period
- Maximal non-invasive support plus  $\geq 1$  of:
  - Apnoea -  $>6/6$ hrs requiring stimulation or  $>1$  PPV/24hrs
  - Sustained oxygen requirement: discretionary at 30%, mandatory at your sites guidelines
  - Respiratory acidosis:  $\text{pH} < 7.2$  and  $\text{CO}_2 > 65$  mmHg (8.66 Kpa)
  - Emergency intubation

## **Extubation Criteria first 10 days:**

- Should be attempted within 24 hours if:
  - MAP  $\leq 8$  and
  - CO<sub>2</sub>  $\leq 55$  and
  - pH  $\geq 7.25$  and
  - FiO<sub>2</sub>  $\leq 40$  and
  - adequate respiratory effort
- Extubation can be attempted from higher settings
- Post extubation support at site discretion

## **Safety Monitoring – Aes and SAEs:**

**Please discuss any potential events with David/Sally/Frazer asap**

### Protocol-defined AEs:

Adverse Event Definition	Reporting Time Frame
Oxygen requirement of $FiO_2 \geq 50\%$ for 3 hours or more*	Within the first 72 hours of life
Infant requiring $FiO_2 > 30\%$ or mechanical respiratory support using an endotracheal tube	Respiratory support assessment only at day of life 28

### Protocol-defined SAEs:

Serious Adverse Event Definition	Reporting Time Frame
Any Death	Within the first 72 hours of life
Pulmonary Haemorrhage	Within the first 72 hours of life
Grade 3 or 4 IVH or PVL	Head ultrasound findings within the first 10 days of life (report based only).
Pneumothorax and/or pneumopericardium. These will be supplemented by data on: <ul style="list-style-type: none"> <li>a) Any chest tube</li> <li>b) Need for new chest tube after arrival in NICU</li> </ul>	Radiographic or lung ultrasound evidence within the first 10 days of life.
Administration of epinephrine or use of chest compressions	Within the first 72 hours of life

All additional AEs/SAEs deemed **related or possibly related** to the intervention must also be reported, **up until** 36 Weeks PMA

**Please report all occurrences to the [Primary Recruiting Site](#)**

## Polar videos

### POLAR Trial: Team Huddle video

Download link (90

MB): [https://player.vimeo.com/external/579735024.hd.mp4?s=7cf469df6c34387aa9b55167512c86d0fad8249c&profile\\_id=175&download=1](https://player.vimeo.com/external/579735024.hd.mp4?s=7cf469df6c34387aa9b55167512c86d0fad8249c&profile_id=175&download=1)

Player link:

[https://player.vimeo.com/external/579735024.hd.mp4?s=7cf469df6c34387aa9b55167512c86d0fad8249c&profile\\_id=175](https://player.vimeo.com/external/579735024.hd.mp4?s=7cf469df6c34387aa9b55167512c86d0fad8249c&profile_id=175)

### POLAR Trial: Static PEEP Group Training Video

Download link (222 MB):

[https://player.vimeo.com/external/579737232.hd.mp4?s=adb9e792b4c5c84fcda6e30b762d4aa17c54ebc2&profile\\_id=175&download=1](https://player.vimeo.com/external/579737232.hd.mp4?s=adb9e792b4c5c84fcda6e30b762d4aa17c54ebc2&profile_id=175&download=1)

Player link:

[https://player.vimeo.com/external/579737232.hd.mp4?s=adb9e792b4c5c84fcda6e30b762d4aa17c54ebc2&profile\\_id=175](https://player.vimeo.com/external/579737232.hd.mp4?s=adb9e792b4c5c84fcda6e30b762d4aa17c54ebc2&profile_id=175)

### POLAR Trial: Dynamic PEEP Group Training video

Download link (247 MB):

[https://player.vimeo.com/external/580552891.hd.mp4?s=87391dd807ad3f8e53139e280e82653456c650a8&profile\\_id=175&download=1](https://player.vimeo.com/external/580552891.hd.mp4?s=87391dd807ad3f8e53139e280e82653456c650a8&profile_id=175&download=1)

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### Parent education video

English Video	Italian Video	French Video
		
Spanish Video	Polish Video	
		