# Comparison of effectiveness two Infant Flow modes (Biphasic tr vs NCPAP) in treatment infants ≤ 1250g

Recruitment status	Prospectively registered
No longer recruiting	☐ Protocol
Overall study status	Statistical analysis plan
Completed	Results
Condition category	Individual participant data
Neonatal Diseases	Record updated in last year
	No longer recruiting  Overall study status  Completed  Condition category

# Plain English summary of protocol

Not provided at time of registration

# Contact information

## Type(s)

Scientific

#### Contact name

Dr Klaudiusz Bober

### Contact details

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# Additional identifiers

## Protocol serial number

N N407 454237

# Study information

### Scientific Title

Comparison of effectiveness two Infant Flow modes (Biphasic tr vs NCPAP) in treatment infants ≤ 1250g. A multicentre, randomised controlled trial

## Acronym

NRSPRCT3

## **Study objectives**

To compare the efficacy and safety of treatment using two Infant Flow modes (Biphasic tr and NCPAP) in two different study groups of very low birth weight (VLBW) infants (elective to avoid intubation and weaning from mechanical ventilation after surfactant).

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Bioethical Committee of the Medical University of Silesia, Katowice, Poland, approved on the 10th July 2008 (ref: KNW/6501-114/08)

## Study design

Multicentre randomised controlled trial

## Primary study design

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Neonatal Diseases: Respiratory

#### Interventions

Newborns weighing between 500-1250g with a gestational age 32 weeks or less, will be categorised into elective or weaning study group and randomly assigned to one of the Infant Flow mode (Biphasic tr or NCPAP) in first six hours of life. Infants that meet criteria for intubation and surfactant will be assigned to the weaning arm of the study. Infants that not meet intubation criteria but required respiratory support within six hours of delivery will be enrolled in the elective arm of the study. Extubation failure in the weaning group is defined as the need for reintubation and mechanical ventilation for any reason within 72 hours of initial extubation.

Treatment failure in the elective group is defined as need for intubation in the first 3 days after first weaning from nCPAP.

Secondary endpoints include: mortality, survival without broncho-pulmonary dysplasia (BPD) or chronic lung disease (CLD), number of days on CPAP, number of days on mechanical ventilation, days on supplemental oxygen, pneumothorax, nasal complications, severe intraventricular hemorrhage, periventricular leukomalacia, retinopathy of prematurity, necrotizing enterocolitis, patient ductus arteriosus and the length of hospital stay.

The sites will be visited regularly by Study Monitors. A database of the results will be maintained by an independent data centre. The results of the study will be blinded to the Investigators, but review every 6 months by an independent Data Safety Monitoring Board according to specific criteria. Prospective power calculations indicated the need for 552 infants to be enrolled. Infants will be followed up until hospital discharge or death.

### Secondary Sponsor:

The Great Orchestra of Christmas Charity (Poland)

Niedzwiedzia St. 2A Warsaw 02-737 Poland http://www.wosp.org.pl

## Intervention Type

Other

### Phase

Not Applicable

## Primary outcome(s)

- 1. Study group A (elective):
- 1.1. Need for intubation within 72 hours after first weaning from nCPAP, indicated by:
- 1.1.1. Laboratory:
- 1.1.1.1. pH<7.2 AND pCO2>8,65kPa (65mmHg)
- 1.1.1.2. SpO2 less than 88% on FiO2 greater than 0.6
- 1.1.2. Clinical:
- 1.1.2.1. Marked increase in respiratory effort
- 1.1.2.2. Persistent apnea
- 1.1.2.3. Need for bag ventilation
- 1.1.2.4. Frequent apnoeas with bradycardia less than 100/min (lack of respiratory efforts for more than 20 seconds, need for stimulation greater than 3/h)
- 2. Study group B (weaning):
- 2.1. Need for intubation within 72 hours after first weaning from mechanical ventilation, indicated by:
- 2.1.1. Laboratory:
- 2.1.1.1. pH<7.2 AND pCO2>8,65kPa (65mmHg)
- 2.1.1.2. SpO2 less than 88% on FiO2 greater than 0.6
- 2.1.2. Clinical:
- 2.1.2.1. Marked increase in respiratory effort
- 2.1.2.2. Persistent apnOea
- 2.1.2.3. Need for bag ventilation
- 2.1.2.4. Frequent apnoeas with bradycardia less than 100/min (lack of respiratory efforts for more than 20 seconds, need for stimulation greater than 3/h)

## Key secondary outcome(s))

- 1. Study group A (elective):
- 1.1. Total respiratory support
- 1.2. Duration of CPAP days
- 1.3. Days oxygen therapy
- 1.4. Length of hospital stay
- 1.5. Pulmonary complications (pneumothorax, interstitial emphysema, broncho-pulmonary dysplasia, chronic lung disease)
- 1.6. Extrapulmonary complications (intraventricular haemorrhage, periventricular leukomalacia, persistent ductus arteriosus, necrotizing enterocolitis, retinopathy of prematurity)
- 1.7. Local (nasal) complications

- 2. Study group B (weaning):
- 2.1. Total respiratory support
- 2.2. Duration of mechanical ventilation days
- 2.3. Duration of CPAP days
- 2.4. Days oxygen therapy
- 2.5. Length of hospital stay
- 2.6. Pulmonary complications (pneumothorax, interstitial emphysema, broncho-pulmonary dysplasia, chronic lung disease)
- 2.7. Extrapulmonary complications (intraventricular haemorrhage, periventricular leukomalacia, persistent ductus arteriosus, necrotizing enterocolitis, retinopathy of prematurity)
- 2.8. Local (nasal) complications

## Completion date

31/12/2012

# Eligibility

## Key inclusion criteria

- 1. Study group A (elective):
- 1.1. Preterm newborns (≤32 gestational weeks)
- 1.2. Birth weight 500-1250g
- 1.3. Any indications to intubation after birth
- 1.4. Signed informed consent by a parent or legal guardian
- 2. Study group B (weaning):
- 2.1. Preterm newborns ( $\leq$  32 gestational weeks)
- 2.2. Birth weight 500-1250a
- 2.3. Clinical signs and symptoms of severe RDS
- 2.4. Indications into surfactant administration after delivery
- 2.5. Signed informed consent by a parent or legal guardian

## Participant type(s)

**Patient** 

# Healthy volunteers allowed

No

## Age group

Neonate

### Sex

All

## Key exclusion criteria

- 1. Study group A (elective):
- 1.1. Preterm newborns (>32 gestational weeks)
- 1.2. Birth weight <500 and >1250g
- 1.3. Presence of congenital malformations

- 1.4. APGAR score < 4 (at 5min)
- 1.5. Incidence of air leaks
- 1.6. The lack of written parental consent
- 2. Study group B (weaning):
- 2.1. Preterm newborns (>32 gestational weeks)
- 2.2. Birth weight <500 and >1250g
- 2.3. Presence of congenital malformations
- 2.4. APGAR score < 4 (at 5min)
- 2.5. Incidence of air leaks
- 2.6. The lack of written parental consent

## Date of first enrolment

15/08/2010

## Date of final enrolment

31/12/2012

# Locations

# Countries of recruitment

Poland

# Study participating centre

Broniewskiego St. 1a/20

Katowice

Poland

40-125

# Sponsor information

## Organisation

Polish Ministry of Science and Higher Education (Poland)

## **ROR**

https://ror.org/05dwvd537

# Funder(s)

## Funder type

Government

## Funder Name

Polish Ministry of Science and Higher Education (Poland)

## **Funder Name**

The Great Orchestra of Christmas Charity (Poland)

# **Results and Publications**

Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## **Study outputs**

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet 11/11/2025 No Yes