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Automatic high flow oxygen support for tiny babies during breathing tube placement – a research study

Submission date
24/03/2025

Recruitment status
Recruiting

Registration date
07/04/2025

Overall study status
Ongoing

Last Edited
15/09/2025

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Few premature babies need placement of breathing tube in the airway as a lifesaving procedure. This procedure is called intubation and one of the most difficult procedure to perform especially in a small premature baby. This procedure has low success rate, as most often the procedure is stopped. One of the main reason to stop the procedure is that baby's oxygen and heart rate goes low during the procedure. Providing breathing support using nose prongs (called as high flow) along with automatic control of oxygen could better support the babies during the procedure and prevent low levels of oxygen. However, we do not know whether providing breathing support using "High flow" along with automatic control of oxygen is better than only providing breathing support using "High flow". With the proposed study, we would like to compare providing breathing support using the "high flow" as compared to providing breathing support using "High flow" along with automatic control of oxygen in babies undergoing intubation procedure to study which method prevents low oxygen levels.

Who can participate?
All preterm babies born in the study center and need placement of breathing tube would be eligible.

What does the study involve?
For the eligible babies , (randomly) would either receive high flow support only or high flow support along with automatic control of oxygen during placement of breathing tube

What are the possible benefits and risks of participating?
Possible benefits: Both groups are likely to receive respiratory support of high flow during the intubation (TI) procedure. This has shown to improve the success rate of first pass intubation attempts. Also, potential to avoid the adverse events associated with multiple intubation attempts.

Possible risks:
There is no risks or burdens for the research participants. Both use of high flow and automated

oxygen is commonly used in neonatal units.
All the research related procedure will be carried out by one of the research team member who is neonatal doctor or nurse.

Where is the study run from?
Study will be run from the neonatal unit, James Cook University Hospital, Middlesbrough, UK

When is the study starting and how long is it expected to run for?
January 2025 to December 2026

Who is funding the study?
VAPOTHERM (UK)

Who is the main contact?
Dr Prakash Kannan Loganathan, pkannanloganathan@nhs.net

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
354944

Protocol serial number
CPMS 67355

Study information

Scientific Title

High flow with Automatic Apnoeic oxygenation for Preterm Intubations - randomised controlled trial

Acronym
HAAPI

Study objectives
Objective: In preterm population <30 weeks birth gestational age receiving semi-elective or elective intubations (placing airway tube) whether provision of high flow automated oxygen support as compared to providing high flow support provides better cardio-respiratory stability (desaturation) and keeping the oxygen levels (Spo2) in the target range?

Ethics approval required
Ethics approval required

Ethics approval(s)
1. submitted 02/04/2025, West Midlands - Edgbaston Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; -; edgbaston.rec@hra.nhs.uk), ref: 25/WM /0054

2. approved 05/08/2025, North of Scotland Research Ethics Committee 1 (Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE, United Kingdom; +44 1224 558458; gram.nosres@nhs.scot), ref: 25/NS/0055

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Preterm intubations

Interventions
All admitted neonates would be screened for study inclusion and exclusion criteria. For those infants who full fill the study criteria will be approached for prospective consent, whenever possible. When prospective consent not possible, recruited infants will be approached for retrospective consent.

Once the decision has been made by the clinical team that a preterm infant needs placement of airway tube (TI), research team would assess the eligibility of the infant for study recruitment. If deemed eligible, Infant will be randomised 1:1 either to High flow with automated oxygen (HAAPI) or only high flow without automated oxygen HF group. Recruited infants in both groups would be placed on nasal high flow therapy of 7L/min at least 5 minutes before the procedure. We chose 7 L/min as this maximum flow rate used in our unit (unit practice). Target SpO2 for infants in both group will be 93% and oxygen (FiO2) in the HF group (standard group) would be under discretion of the attending clinical team and the infants in HAAPI group will be adjusted

by the device. Infants in both groups would be connected to pulse oximetry sensor from the high flow device, which would enable us to collect continuous SpO2 and pulse rate data. Infants in both groups will also be connected to pulse oximeter sensor from the bedside monitors, which would allow the clinical team to monitor the vitals. High flow support in both groups will be continued until the
procedure is completed.

One of the member of the research team will collect the data contemporaneously. Study workbook provides all the data that will be collected for the study. Research team member blinded to the study randomisation and interventions will analyse the data related to primary and secondary outcomes.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Time to oxygen desaturate defined as drop in oxygen saturation (Spo2) by 20% from baseline for duration of the intubation attempt

Key secondary outcome(s))
1. Total number of intubation attempts before successfully placing the breathing tube
2. Severity of desaturation: Change in baseline oxygen saturation prior to the intubation procedure to lowest Spo2 value during the intubation procedure measured using continuous pulse oximetry
3. Lowest and highest oxygen saturation (Spo2) during the procedure measured using continuous pulse oximetry
4. Proportion of time Spo2 within the target range 90-95% measured using continuous pulse oximetry
5. Proportion of time Spo2 above 95% measured using continuous pulse oximetry
6. Proportion of time oxygen saturation below 80%: Time below Spo2 80%/ Total duration of intubation procedure measured using continuous pulse oximetry

Completion date
31/12/2026

Eligibility

Key inclusion criteria
1. Birth gestational age < 30 weeks based on mother’s last menstrual period or best obstetric estimate with first trimester ultrasound
2. Need for semi/elective intubation in the neonatal unit and the need ascertained by the neonatal team

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Neonate

Upper age limit
30 weeks

Sex
All

Key exclusion criteria
Current exclusion criteria as of 15/09/2025:

1. Perceived difficult airway by the medical team.
2. Previous intubation episode with more than two intubation attempts for successful intubation by an experienced intubators (Neonatal Consultant).
3. Contraindication to High Flow Nasal Cannula (e.g., congenital nasal anomaly, congenital diaphragmatic hernia, or abdominal wall defect).
4. Delivery room intubations.
5. Emergency intubations as ascertained by the clinical team (e.g. Heart rate <100/min, apnea at the time of procedure).
6. LISA/MIST technique of surfactant administration
7. Infants diagnosed with pneumothorax needing needle or chest tube drainage.
8. Infants with cyanotic heart disease.

_____

Previous exclusion criteria:

1. Perceived difficult airway by the medical team.
2. Previous intubation episode with more than two intubation attempts for successful intubation.
3. Delivery room intubations.
4. Emergency intubations as ascertained by the clinical team (e.g. Heart rate < 100/min, apnea at the time of procedure).
5. LISA/MIST technique of surfactant administration
6. Infants diagnosed with pneumothorax needing needle or chest tube drainage.
7. Infants with cyanotic heart disease.

Date of first enrolment
01/10/2025

Date of final enrolment
30/12/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
James Cook University Hospital
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

Study participating centre
Medway NHS Foundation Trust
Medway Maritime Hospital
Windmill Road
Gillingham
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ME7 5NY

Sponsor information

Organisation
South Tees Hospitals NHS Foundation Trust

ROR
https://ror.org/02js17r36

Funder(s)

Funder type
Industry

Funder Name
VAPOTHERM, INC.

Results and Publications

Individual participant data (IPD) sharing plan
Deidentified individual participant data will be made available, in addition to study protocols, the statistical analysis plan, and the consent form. The data will be made available upon publication to researchers who provide a methodologically sound proposal and research ethics board approval. Proposals should be submitted to pkannanloganathan@nhs.net

IPD sharing plan summary
Available on request