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Comparison of patient-device interface types in breathing support of newly born infants

Submission date
28/05/2021

Recruitment status
No longer recruiting

Registration date
01/06/2021

Overall study status
Completed

Last Edited
09/02/2024

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Continuous positive airway pressure (CPAP) is the most commonly used device for supporting the breathing of babies. However, providing effective CPAP in preterm infants have been challenging, often related to problems associated with the nasal interface. Most neonatal intensive care units (NICUs) use short nasal prongs to deliver supplemental oxygen and CPAP in neonates. These prongs are effective and safe but have the potential to cause nasal septal pressure injury and pressure leak around the nares. The RAM cannula (a canula that connects the device to the baby nose) was approved by the Food and Drug Administration for providing supplemental oxygen. It was soon adopted by clinicians to provide CPAP, largely because of its perceived ease of use and less nasal (septal) injury. Compared with the standard nasal interface for CPAP, the RAM cannula is made of softer material with a thin prong wall resulting in a larger caliber and less nasal trauma. However, there is increasing concern that the RAM cannula might be less effective in supporting the breathing of babies.
This study will compare how effective and safe these two devices are.

Who can participate
This study will include babies born at our center

What does the study involve?
Participants will be randomly allocated to receive RAM canula or nasal prongs. Participants will be closely monitored until the end of their hospital stay.

What are the possible risks and benefits?
Since both devices are used in our unit , there is no extra risks involved , however if our trial showed that one of these device is better, we will use only that device for our babies.

Where is the study run from?
Jordan University Hospital (Jordan)

When is the study starting and how long is expected to run for?

Who is funding the study?
Investigator initiated and funded

Who are the main contact?
Prof. Manar Al-lawama, manar-76@hotmail.com

Contact information

Type(s)
Scientific

Contact name
Prof Manar Al-lawama

ORCID ID
https://orcid.org/0000-0001-9313-112X

Contact details
Ahmad Ahajjaj street
Amman
Jordan
11937
+962 799068565
m.allawama@ju.edu.jo

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
10/2021/10919

Study information

Scientific Title
RAM canula versus short nasal prongs for management of respiratory distress in neonatal patients: a randomized trial

Acronym
ProRAM Study

Study objectives
The use of RAM canula as an interface in neonates with respiratory distress is as effective as nasal prongs in providing nasal CPAP, easier for the nursing care, and causes less physical injury for the nose of the newborn infant

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/05/2021, Ethical Committee at The University of Jordan Hospital (Jordan University Hospital, Queen Rania street, PO. Box: 11943, Amman-Jordan; +962 65353666; juhwebsite@ju.edu.jo), ref: 10/2021/10919

Study design
Single center interventional randomized conrolled study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Manegment of neonates with respiratory dsitress

Interventions
The included neonates will be classified into 2 groups, less than 32 weeks GA, and equal to 32 or more GA.
Within each group, the babies will be randomly allocated to be put on RAM canula or nasal prongs.
The demographic data of the included neonates will be collected.
Clinical data will include: presentation, final diagnosis, and respiratory management needed. Chest x-ray findings, blood gas results. Complications, other neonatal morbidities including intraventricular hemorrhage length of stay, and mortality.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
RAM canula, short nasal prongs

Primary outcome(s)
Measured using data from the patients' charts and laboratory database at discharge:
1. Duration on CPAP
2. Need for escalation of respiratory support
3. Surfactant administration
4. Mortality before discharge

Key secondary outcome(s))
Measured using data from the patients' charts and laboratory database at discharge:
1. Nasal injury during respiratory support
2. Pneumothorax during respiratory support

3. Length of hospital stay
4. Chronic Lung disease at 36 weeks Post conceptional age

Completion date
30/09/2021

Eligibility

Key inclusion criteria
Neonates who have respiratory dsitress at birth

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Key exclusion criteria
1. Noenataes who present with respiratory distress after being transferred out of the delivery room
2. Outborns
3. Neonates diagnosed prenatally to have lung malformation
4. Neonates who are diagnosed prenatally or found at birth to have major congenital anomalies

Date of first enrolment
06/06/2021

Date of final enrolment
30/08/2021

Locations

Countries of recruitment
Jordan

Study participating centre
Jordan University Hospital
Queen Rania Street
Amman
Jordan
11943

Sponsor information

Organisation
University of Jordan

ROR
https://ror.org/05k89ew48

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		10/01/2024	09/02/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes