

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

<b>Submission date</b> 28/05/2021	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 01/06/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 09/02/2024	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> 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 cannula 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 cannula 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 devices 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**  
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## 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 controlled study

**Primary study design**

Interventional

**Study type(s)**

Treatment

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

Management of neonates with respiratory distress

**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?
<a href="#">Results article</a>		10/01/2024	09/02/2024	Yes	No