Heliox delivered by high flow nasal cannula in infants with acute bronchiolitis

Submission date	Recruitment status	[X] Prospectively registered
16/01/2017	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
26/01/2017	Completed	Results
Last Edited	Condition category	Individual participant data
26/01/2017	Respiratory	Record updated in last year

Plain English summary of protocol

Background and study aims

Respiratory syncytial virus bronchiolitis is a type of chest infection caused by a virus that affects infants, causing small tubes in the lungs to swell. Symptoms include a high temperature (fever), cough and difficulty breathing. Some infants have to be hospitalized in order to be given oxygen through a tube that goes over their nose or face to improve their breathing. Heliox (a mixture of oxygen and helium gases) may be given in order to improve breathing and provide more movement of air through airways that have become smaller due to the infection causing swelling in the lungs. Heliox is normally given using a ventilator which does the job of breathing for the patient through a tube inserted into the mouth. However, there are less invasive methods to provide Heliox such as through a high flow nasal cannula (HFNC) which continuously delivers air through a tube that is inserted into the nostrils. The aim of this study is to evaluate whether Heliox, when delivered through a HFNC, can help improve airflow for infants with bronchiolitis and decrease the need for more complicated therapies.

Who can participate?
Infants who are hospitalized for bronchiolitis

What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group are given the Heliox therapy continuously for 24 hours through a HFNC. Those in the second group are given oxygen continuously for 24 hours through a HFNC. Participants are followed up at the end of the intervention (after 24 hours) to see if there are improvements in the amount of oxygen found in their blood samples and if their breathing improved.

What are the possible benefits and risks of participating? Participants may benefit from improvements in their breathing and it may relieve their symptoms. There is a risk that participants may feel discomfort when providing blood samples.

Where is the study run from? Al Salam Hospital (Kuwait)

When is the study starting and how long is it expected to run for? October 2016 to February 2018

Who is funding the study? Investigator initiated and funded (Kuwait)

Who is the main contact? Professor Wael Seliem wseliem@hotmail.com

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

142281

Study information

Scientific Title

Heliox delivered by high flow nasal cannula improves oxygenation in Infants with respiratory syncytial virus acute bronchiolitis

Study objectives

The aim of the study is to evaluate whether the use of Heliox would result in an improvement of gas exchange when delivered through a high flow nasal cannula continuously (HFNC) in infants with respiratory syncytial virus (RSV) acute bronchiolitis.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Mansoura University Faculty of Medicine MU, 25/12/2016, ref: 142281/2016

Study design

Single centre randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Respiratory syncytial virus acute bronchiolitis

Interventions

Participants are randomly allocated to one of four blocks. These blocks are randomly allocated to one of two groups.

Group one (the intervention group) receive Heliox therapy (70:30) delivered through high flow nasal cannula continuously for 24 hours. If the oxygen saturation was kept \leq 93% despite the fraction of inspired oxygen of 30%, an increment of 5% was done to keep saturation >93%.

Group two (the control group) receive an air-oxygen mixture at 8 L/minute through a high flow nasal cannula continuously for 24 hours. If the oxygen saturation was kept \leq 93% despite the fraction of inspired oxygen of 30%, an increment of 5% was done to keep saturation >93%.

Participants are followed up at the end of the intervention (24 hours) to see if there is improvement in gas exchange and breathing.

Intervention Type

Supplement

Primary outcome(s)

- 1. Partial arterial pressure and partial arterial oxygen are assessed using arterial blood samples at baseline, 2 hours and 24 hours
- 1.1. Oxygen saturation is assessed using pulse Masimo SET pulse oximeter continuously throughout the intervention
- 2. Respiratory distress is measured by the Modified Wood's Clinical Asthma Score at 2 hours and 24 hours

Key secondary outcome(s))

Length of hospital stay is measured by reviewing patient notes at the end of hospital stay.

Completion date

15/02/2018

Eligibility

Key inclusion criteria

- 1. Infants aged from 1 month to 2 years old
- 2. Patients who are admitted to the pediatric high dependency unit, with RSV acute bronchiolitis diagnosed clinically confirmed by laboratory testing
- 3. Display the diagnostic criteria of bronchiolitis including cough, tachypnea, chest retraction, prolonged expiratory time, sibilant rhonchi, and hyperinflation of the lungs
- 3. Cannot maintain oxygen saturation ≥ 93% in room air and require supplemental oxygen on admission to hospital

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

1 months

Upper age limit

2 years

Sex

Αll

Key exclusion criteria

- 1. No informed consent obtained
- 2. Require mechanical ventilation
- 3. Congenital heart defect that is haemodynamically significant (significant left-to-right shunting with or without pulmonary hypertension or right-to-left shunting)
- 4. Underlying chronic lung disease including bronchopulmonary dysplasia and previously diagnosed hyper-reactive airway diseases

Date of first enrolment

15/02/2017

Date of final enrolment

15/11/2017

Locations

Countries of recruitment

Kuwait

Study participating centre Al Salam International Hospital

Port Said St Bneid Al Qar Dasma

Sponsor information

Organisation

Mansoura University Children Hospital

ROR

https://ror.org/01k8vtd75

Funder(s)

Funder type

Not defined

Funder Name

Investigator initiated and funded.

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication

IPD sharing plan summary

Other

Study outputs

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

Participant information sheet 11/11/2025 No Yes