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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
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 ≤ 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 ≤ 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 measure
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

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

Overall study start date
20/10/2016

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

Age group
Child

Lower age limit
1 Months

Upper age limit
2 Years

Sex
Both

Target number of participants
80

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
Kuwait City
Kuwait
35151

Sponsor information

Organisation
Mansoura University Children Hospital

Sponsor details
60 El Gomhoria Street
Mansoura
Egypt
35516

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01k8vtd75

Funder(s)

Funder type

Not defined

Funder Name
Investigator initiated and funded.

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
15/02/2019

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