

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

<b>Submission date</b> 16/01/2017	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 26/01/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 26/01/2017	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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**  
Prof Wael Seliem

**ORCID ID**  
<http://orcid.org/0000-0003-1304-5809>

**Contact details**  
Al Salam Hospital  
Port Said St.  
Bneid Al Qar Dasma  
Kuwait  
Kuwait  
35151  
+965 9667 6695  
wseliem@hotmail.com

## 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  $\leq 93\%$  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 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  $\geq 93\%$  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