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Investigating the safety and oxygen-savings of a new nasal cannula used to treat severe pneumonia in children in low-resource settings

Submission date
10/07/2020

Recruitment status
No longer recruiting

Registration date
15/07/2020

Overall study status
Completed

Last Edited
17/08/2022

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims
This study is investigating how oxygen (a clean, odorless gas necessary for life) is given to children with low oxygen levels due to lung infections like pneumonia. The aim is to learn more about a new device that is loosely worn over the nose (nasal mask) compared to the current standard of care: a nasal cannula (a lightweight tube with two prongs placed in the nose to provide a mixture of air and oxygen). This mask is unique in that its form and fit provides more nasal coverage to the patient while loosely sitting on the nose. This means that the mask takes up more space over the children's noses (and goes onto their cheeks), but it is not tightly secured. The new nasal mask device is used to decrease the total amount of oxygen needed for adequate oxygen supply in sick children with low oxygen levels due to lung infections like pneumonia.

Who can participate?
Any child aged between 1 and 6 years old admitted to Mulago Hospital with pneumonia who has low oxygen levels can be enrolled in this study.

What does the study involve?
Children who participate in this study will help assess whether the new nasal mask added over the standard method of care (nasal cannula: a lightweight tube with two prongs placed in the nose to provide a mixture of air and oxygen) safely and adequately delivers oxygen. Children enrolled will receive the same treatment as children not enrolled in the study. In addition to what is normally provided to patients, additional physical and blood testing will take place to ensure the safety of the children participating. These additional safety and monitoring tests are not normally provided during routine care at Mulago Hospital. For children in this study, a Study Nurse will complete a form to collect information about the child's hospitalization, including how the child's body is working, what problems are causing the child to be sick, and any treatments that are given to the child.

During the study, children will use the conventional nasal cannula alone for 1 hour and use the nasal cannula with the mask placed over it for a second hour. The order in which the children

received the mask in combination with the nasal cannula either during the first or during the second hour will be chosen randomly. After the two-hour test period, oxygen treatment will be continued with the standard nasal cannula alone. The study pediatrician or nurse will draw blood three times during the study (once at the beginning, once after the first hour wearing the cannula, or mask and cannula, and once at the end). Some of these blood tests will be done as part of standard care but some will done in addition to standard care to ensure the children's safety. The extra tests are called blood gases. These tests measure the oxygen and carbon dioxide levels in the children's blood, which help doctors monitor the children's health while they receive oxygen therapy. Other tests include oxygen monitoring, which will be done via a tiny pain-free device attached to the skin; a physical exam, which includes simple tests like listening to children's lungs and measuring their weight; and additional tests like heart rate, temperature, respiratory rate, and blood pressure.

What are the possible benefits and risks of participating?
There is a small possibility that the device may not deliver oxygen as well as the standard device. The children will be monitored continuously during the study to detect any medical problems, such as a drop in the oxygen level. The children will receive the same clinical care as children not enrolled in the study as well as additional physical and blood testing to ensure their safety. The nasal mask has the potential to be slightly uncomfortable for the children, but should not cause any pain. The additional physical tests like oxygen monitoring should not cause any pain. The children may experience minor discomfort (like a finger prick) from the four blood draws (two at the beginning, one in the middle, one at the end of the study). The total amount of blood drawn will be minimal (up to 1 teaspoon), and follows recommendations from medical experts, based on the weight of the child.

The information collected during this study will help to assess the novel nasal cannula's ability to safely and efficiently administer oxygen. For this study, the novel nasal cannula will be tested for 1 hour followed by the standard nasal cannula. Once this study is published and the equipment is improved, a subsequent research study may help to test if efficient oxygen helps patients have improved health outcomes or a shorter hospital stay in the future. This may potentially help other children in Uganda and elsewhere in the future, for example, through access to better equipment and treatments.

Where is the study run from?
Investigators and collaborators from the Department of Pediatrics and Child Health at Mulago Hospital, and Makerere University carried out this project at Mulago Hospital (Uganda).

When is the study starting and how long is it expected to run for?
From November 2018 to May 2019

Who is funding the study?
Intellectual Ventures Global Good Fund (USA)

Who is the main contact?
Dr. Michael Hawkes
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Version 1

Study information

Scientific Title

Oxygen sparing and clinical safety of nasal reservoir cannula for the treatment of pediatric hypoxemic pneumonia in a low-resource setting

Study objectives
We hypothesized that a novel oxygen-sparing nasal reservoir cannula (RC) would be well-tolerated, safe, and efficacious among Ugandan children hospitalized with hypoxemic pneumonia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 26/02/2018, Mulago Hospital Research and Ethics Committee (PO Box 7051, Kampala, Uganda; +256 415540081; admin@mulago.or.ug), ref: MHREC 1075
2. Approved 29/06/2018, Western Institutional Review Board (1019 39th Avenue SE Suite 120, Puyallup, WA 98374-2115, USA; +1 (360) 252-2500; clientservices@wirb.com), ref: 1188233
3. Approved 06/05/2019, University of Alberta Health Research Ethics Board - Biomedical Panel (308 Campus Tower, 8625 - 112 Street, Edmonton, Alberta, Canada T6G 1K8; +1 780-492-0459; reoffice@ualberta.ca), ref: Pro00089057

Study design
Prospective open-label randomized controlled cross-over pilot study

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Hypoxemic pneumonia

Interventions
The study will test an oxygen-sparing reservoir cannula which fits over a standard nasal cannula and increases dead space to recapture a portion of expelled oxygen. This will be compared to the use of a standard nasal cannula alone. The study takes place over 2 h with a randomised crossover design where eligible patients are randomly assigned to receive one of either conventional nasal cannula alone or the nasal cannula with the mask placed over it for 1 h, followed by the alternate treatment for a second 1 h. Randomization by blocks of 4 was employed, in order to balance group assignment over time, using a computer-generated list. Treatment assignment was recorded on paper and kept in sequentially numbered, sealed,

opaque envelopes in a locked cabinet. After patient stabilization and informed consent, the next envelope was drawn by a study investigator. The trial was not blinded.

The study pediatrician or nurse will take capillary blood gas three times during the study (once at the beginning, once after the first hour wearing either the cannula or mask + cannula, and once at the end). Other tests that will be carried out on participants include oxygen monitoring (using a finger pulse oximeter), a physical exam (including auscultation and weight), and additional tests like heart rate, temperature, respiratory rate, and blood pressure.

Intervention Type
Device

Phase
Phase II

Drug/device/biological/vaccine name(s)
Oxygen sparing reservoir cannula device

Primary outcome measure
Clinical safety of the reservoir cannula (RC) was assessed using CO2 retention, as measured by the change in pCO2 on capillary blood gas measurement after 1 h on RC or standard nasal cannula (SNC). The change was calculated using measurements taken at baseline and 1 hour later.

Secondary outcome measures
1. Incidence of clinical adverse events, including: pCO2 above the normal range (>45 mmHg); lactate above the normal range (>3 mmol/l); acidosis (pH <7.35); and refractory hypoxemia (SpO2 <90%) despite supplemental oxygen therapy at any time on RC, measured from capillary blood gas at baseline, 1, and 2 h
2. Longitudinal changes in pCO2, pH, and lactate measured from capillary blood gas at baseline, 1, and 2 h
3. RC efficacy measured using oxygen utilization and SpO2 (using a finger pulse oximeter) at several O2 flow rates on either RC or standard nasal cannula (SNC) alone, at baseline, 1, and 2 h

Overall study start date
26/02/2018

Completion date
24/05/2019

Eligibility

Key inclusion criteria
1. Aged ≥1 year and ≤6 years
2. Severe pneumonia based on World Health Organization (WHO) criteria 2
3. SpO2 ≥85% and <94% by pulse oximetry on room air
4. Hospital admission indicated based on clinician judgment
5. Body weight ≥8 kg and ≤26 kg

Participant type(s)

Patient

Age group
Child

Lower age limit
1 Years

Upper age limit
6 Years

Sex
Both

Target number of participants
16

Total final enrolment
16

Key exclusion criteria
1. Hypercapnia (pCO_2 >55 mmHg) on room air
2. pH <7.20 (capillary blood gas)
3. Lactate >3 mmol/l (capillary blood gas)
4. SICK score 20 > 2.4
5. Hemoglobin <7 g/dl
6. Facial abnormalities or trauma precluding use of nasal prongs
7. Requiring intubation or positive-pressure ventilation
8. Suspected or known pneumothorax
9. Hemodynamic instability
10. Failure to respond to oxygen after trial period (SpO_2 <90%, measured after 10 mins of oxygen therapy at 2 l/min)

Date of first enrolment
20/11/2018

Date of final enrolment
21/05/2019

Locations

Countries of recruitment
Uganda

Study participating centre
Mulago National Referral Hospital
Plot 6
Lourdel Road
Nakasero

Kampala
Uganda
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Sponsor information

Organisation
Intellectual Ventures (United States)

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Sponsor type
Industry

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http://www.intellectualventures.com/

ROR
https://ror.org/05evsnd79

Funder(s)

Funder type
Industry

Funder Name
Intellectual Ventures Global Good Fund

Results and Publications

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

Intention to publish date
09/07/2020

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available because informed consent for disclosure of individual patient data was not obtained from study participants. Aggregate-level data will be made available upon reasonable request as Excel spreadsheets from the corresponding author, Dr. Michael Hawkes, at mthawkes@ualberta.ca. Data are guaranteed to be available up to 5 years post-study end date. Data may be available upon request after 5 years but cannot be guaranteed. Data will be shared with members of the scientific community upon reasonable request via email for the purpose of confirmation of validity of the analysis or secondary data analysis. All data shared will be anonymized and presented in aggregate.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	31/08/2020	03/09/2020	Yes	No
Protocol file	version 1	01/07/2018	17/08/2022	No	No