ISRCTN48562837 https://doi.org/10.1186/ISRCTN48562837

High concentration oxygen therapy in pediatric asthma exacerbation

Submission date 15/06/2016	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 17/06/2016	**Overall study status** Completed	
Last Edited 17/05/2017	**Condition category** Respiratory	

Plain English summary of protocol

Background and study aims
Asthma Is a common long term health condition caused by inflammation of the bronchi, small tubes that carry air in and out of the lungs. The airways can become narrow if the sufferer comes into something that “triggers” their asthma – for example animal fur, pollen, viral infection and exercise. This can cause symptoms such as coughing, wheezing, tightness of the chest and feeling breathless. Occasionally, asthma symptoms can gradually or suddenly get much worse. This is called an asthma attack. Severe attacks may require hospital treatment and, in extreme cases, can even lead to death. This study is looking at the use of oxygen in children who are having an asthma attack. The researchers are investigating whether the amount of oxygen used affects the carbon dioxide in children suffering from an asthma attack and whether it makes their asthma worse and/or results in their hospitalization.

Who can participate?
Children 2-18 years of age suffering from a moderate to severe asthma attack and are coming to the emergency room (ED)

What does the study involve?
Participants are randomly allocated to one of two groups. Those in group 1 receive 100% oxygen as part of their treatment. Those in group 2 receive titrated oxygen to keep that oxygen level between 92 to 95% while they are receiving their nebulization treatments.

What are the possible benefits and risks of participating?
There are no direct benefits from participating in this study. There are no risks from participating in this study as the oxygen levels are always kept in the normal range in both groups.

Where is the study run from?
The Children's Hospital at Montefiore, Bronx, New York (USA)

When is study starting and how long is it expected to run for?
December 2013 to May 2016

Who is funding the study?
Pediatric Critical Care Division, Children's Hospital at Montefiore (USA)

Who is the main contact?
Dr Bhavi Patel

Contact information

Type(s)
Public

Contact name
Dr Bhavi Patel

Contact details
The Children's Hospital at Montefiore
3415 Bainbridge Avenue
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United States of America
10467

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2015-4431

Study information

Scientific Title
Randomized clinical trial of high concentration oxygen therapy versus titrated oxygen therapy in pediatric asthma exacerbation

Study objectives
High concentration oxygen leads to rise in transcutaneous carbon dioxide in acute exacerbation of asthma in the pediatric population.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Albert Einstein College of Medicine Institutional Board Review, 22/04/2015, ref: 2015-4431

Study design

Single-center randomized prospective double-blind clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Pediatric asthma exacerbation

Interventions
Children 2 to 18 years with previously diagnosed asthma with moderate to severe asthma exacerbation (asthma score > 5) were randomized to high concentration oxygen therapy (100% oxygen via face mask at >4L/min) or titrated oxygen therapy (titrated up from 21% via a blender continuously) to maintain saturations between 92 to 95% while receiving their nebulized treatments.

Randomization was based on computer randomization sequence program generated by the biostatistician.

Intervention Type
Other

Primary outcome measure
Rise in transcutaneous carbon dioxide, measured via a transcutaneous carbon dioxide monitor at 0, 20, 40, 60 minutes and then every 30 minutes till disposition decision was reached by the ED physician

Secondary outcome measures
1. Change of > 4 mmHg PtCO2 and > 38 mmHg PtCO2 measured via a transcutaneous Co2 monitor at 0, 20, 40, 60 minutes and then every 30 minutes till disposition decision was reached by the ED physician
2. Change in asthma score, measured via a validated respiratory score tool used by the hospital as part of the asthma treatment pathway at 0, 20, 40, 60 minutes and then every 30 minutes till disposition decision was reached by the ED physician
3. Admission rates

Overall study start date
01/12/2013

Completion date

18/05/2016

Eligibility

Key inclusion criteria
Patients between 2 to 18 years with previous medical diagnosis of asthma presenting with moderate to severe asthma exacerbation with asthma score > 5

Participant type(s)
Patient

Age group
Child

Lower age limit
2 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
104

Key exclusion criteria
1. Disorders with hypercapnic respiratory failure such as neuromuscular disease, chest wall restriction, or obesity hypoventilation
2. Unconscious patient
3. Pregnancy
4. Receiving sedatives/depressants
5. History of congenital heart disease
6. Disease of cardiac, renal, or hepatic systems
7. History of smoking

Date of first enrolment
01/08/2015

Date of final enrolment
18/05/2016

Locations

Countries of recruitment
United States of America

Study participating centre

The Children's Hospital at Montefiore
3415 Bainbridge Avenue
Bronx
New York
United States of America
10467

Sponsor information

Organisation
Pediatric Critical Care Department

Sponsor details
3415 Bainbridge Avenue
Bronx
New York
United States of America
10467

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Department of Pediatric Critical Care at the Children's Hospital at Montefiore (CHAM)

Results and Publications

Publication and dissemination plan
Hope to get manuscript published in the next 6 months.

Intention to publish date
31/12/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available