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Impact of a non-invasive positive pressure ventilation protocol in comparation with non-protocolised strategy of ventilation in children hospitalised with acute respiratory failure

Submission date
20/12/2016

Recruitment status
No longer recruiting

Registration date
06/01/2017

Overall study status
Completed

Last Edited
20/01/2020

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims
An acute lower respiratory infection is the name given to a group of sudden chest infections, such as pneumonia. They are a leading cause of death and illness in children and adults, and are one of the most frequent causes of death in children's wards. Non-invasive Positive Pressure Ventilation (NIPPV) is a type of treatment that helps patients to breathe by way of a face mask or tubes in the nose. NIPPV has proven to be useful in the treatment of children with acute lower respiratory infection, helping to reduce strain on the muscles that control breathing and reducing the need for invasive treatment (inserting a tube into the lungs). Despite this, the best way of monitoring and using this treatment is not known. The aim of this study is to look at the effectiveness of a new NIPPV monitoring protocol.

Who can participate?
Children aged between 3 months and 2 years old who are in hospital with a chest infection.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group are monitored using the new NIPPV monitoring protocol. This involves close monitoring for the first 24 hours and then regular assessments at specified timepoints. At each timepoint, patients are assessed to evaluate the severity of their symptoms. Those in the second group are monitored as usual with no specified strategy of management. At the start of the study and during follow up (the time they are in hospital), the length of time participants in each group spent on NIPPV is recorded, as well as the need for additional oxygen. The length of hospital stay for participants in each group is also recorded.

What are the possible benefits and risks of participating?
There are no direct benefits or risks associated with participating.

Where is the study run from?
Hospital Josefina Martinez (Chile)

When is the study starting and how long is it expected to run for?
June 2013 to October 2013

Who is funding the study?
Hospital Josefina Martinez (Chile)

Who is the main contact?
Mr Yorschua Jalil
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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
2886

Study information

Scientific Title
Impact of a non-invasive positive pressure ventilation protocol in children hospitalized with acute respiratory failure: A randomized clinical trial

Study objectives

The use of a non invasive positive pressure ventilation protocol in children under two years old, hospitalized for an acute respiratory failure could reduce the work of breathing, length in hospital and use of non-invasive positive pressure ventilation in contrast with non protocol use.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee of the South Eastern Metropolitan Health Service. Hospital "Dr. Sotero del Rio", 06/07/2013, ref: 2886

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
Acute lower respiratory infection

Interventions
Patients included in the study are randomized to management of ventilatory support according to usual medical criteria (control group or CG) or to protocolized management of ventilatory support (protocol group or PG).

Protocol group: Participants are monitored using the protocol of ventilatory support. This protocol is based on the standardization of the criteria to initiate ventilatory support, the maintenance of this for 24 hours without pressure drops and the maintenance of continuous support until its definitive suspension. The protocol includes 7 assessment stages:
1. Initial assessment to decide on the use of NIV (physician)
2. Assessment after one hour of connection (physician and/or Respiratory therapist /Kinesiologist)
3. Assessment after three hours of connection (physician and/or Respiratory therapist /Kinesiologist)
4. Assessment after 24 hours of connection (physician and/or Respiratory therapist/Kinesiologist)
5. Assessment after 4 hours of having achieved pressure drop to IPAP 10 / EPAP 6 cmH2O (physician and/or Respiratory therapist/Kinesiologist)

6. Assessment after 4 hours of having achieved change from ventilatory mode to CPAP 6 (physician and/or Respiratory therapist/Kinesiologist)
7. Assessment after 4 hours after disconnection of NIV (physician)
At all stages of the protocol, the Modified Wood Scale score (MWS), ventilatory parameters (Mode, IPAP, EPAP, CPAP, Ti and Rf programmed as appropriate) and SaFi index (SatO2 / FiO2) are considered. In patients with an unfavorable clinical course, modifications are made to the ventilatory support according to the criteria of the treating physician. When there is an increase in the MWS score over the last score recorded, this is considered as a worsening of the clinical condition. For the purposes of comparative analyses between the two groups, assessments 1 and 2 are used since they are the only ones with a common record given the nature of the interventions for the CG.

Control group: Assessments for control group participants are determined by the treating physician according to best medical practice. Participants are followed up at the same timepoints as those in the protocol group.

For participants in both groups, the follow up period is until the time of discharge from hospital or worsens, requiring more advanced support.

Intervention Type
Mixed

Primary outcome measure
1. Time of connection to Non Invasive Positive Pressure ventilation (NIPPV) measured in hours by a record table (designed for the purpose of this study) at baseline, and follow up until withdrawal occurs
2. Duration of hospitalization measured in hours by a record table (designed for the purpose of this study) at baseline, and follow up until discharge occurs
3. Use of additional oxygen after withdrawal of NIPPV measured in hours by a record table (designed for the purpose of this study) at baseline, and follow up until discontinuation

Secondary outcome measures
1. Severity of respiratory symptoms is measured using the Modified Wood Scale Score (MWS) at baseline and 1 hour after NIPPV start
2. Severity of respiratory symptoms in the protocol group is measured using the Modified Wood Scale Score (MWS) at baseline and 1, 24 hours after NIPPV start and at 4 hours after change of mode to CPAP prior to disconnection
3. Oxygenation in the protocol group after connection to NIPPV measured using the SAFI index at 1 and 24 hours after NIPPV start
4. Proportion of intubation (Need of Invasive ventilator support) measured frequency and % at the end of follow up

Overall study start date
15/03/2013

Completion date
31/10/2013

Eligibility

Key inclusion criteria

1. Hospitalized in Hospital Josefin Martinez
2. Aged between 3 months and 2 years
3. Diagnosis of acute lower respiratory infection
4. Need of NIPPV, according to Modified Wood Scale (MWS) with score ≥ 4 points

Participant type(s)
Patient

Age group
Child

Lower age limit
3 Months

Upper age limit
2 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Prior use of NIV
2. History of respiratory comorbidities

Date of first enrolment
01/05/2013

Date of final enrolment
30/10/2013

Locations

Countries of recruitment
Chile

Study participating centre
Hospital Josefina Martinez
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Sponsor information

Organisation
Hospital Josefina Martinez

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Sponsor type
Hospital/treatment centre

Website
http://www.hospitaljosefinamartinez.cl

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Hospital Josefina Martinez

Results and Publications

Publication and dissemination plan
Planned submission of the study for publication in a high impact peer reviewed journal in the next 2 to 3 months.

Intention to publish date
31/12/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Yorschua Jalil (yjalilcontreras@gmail.com)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		05/01/2017	18/01/2017	No	No