High Flow Nasal Cannula therapy for infants with Bronchiolitis: a randomized controlled trial

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To evaluate the effect on severity of dyspnoea of administration of oxygen through High Flow Nasal Cannula compared to oxygen delivery through Low Flow Nasal Prongs in children hospitalized for bronchiolitis with moderate to severe dyspnoea.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Viral infectious disorders
Study type	Interventional

Summary

ID

NL-OMON42950

Source
ToetsingOnline

Brief title
High flow in bronchiolitis

Condition

- Viral infectious disorders
- Respiratory tract infections

Synonym
Bronchiolitis, luchtweginfectie

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: Isala

Intervention

Keyword: bronchiolitis, Children, High Flow, Infants

Outcome measures

Primary outcome

Decrease in dyspnoea severity, depicted by decrease in PEWS with >= 2 points within 24 hours. PEWS will be assessed at t=0, 1, 2 and 3 hours and thereafter at least every three hours during hospitalisation, or more frequent, as indicated.

Secondary outcome

Respiratory rate, retractions, heart rate, conscious state, oxygen saturation, FiO2, temperature, Comfort (FLACC), ability to feed, tube feeding, intravenous fluids, bloodgas analysis (in case of PEWS >= 8, or as indicated by the treating physician), mechanical ventilation, referral to PICU, length of hospitalization.
By measuring these different variables we are able to compose several composite dyspnoea scores other than the PEWS (i.e. RDAI Respiratory Distress Assessment Instrument, PRAM Pediatric Respiratory Assessment Measurement). None of these scores is sufficiently validated, however by measuring the most frequently used, we will enable comparison of our data with other studies.

Study description

Background summary

Bronchiolitis is a common respiratory tract illness in young children, usually of viral origin, causing a clinical picture of dyspnoea due to airway obstruction and feeding problems.[Florin 2016] During winter seasons, bronchiolitis is an important reason for hospital admissions in young children.

Since no pharmacological intervention has been proven effective, treatment is supportive, existing of oxygen supplementation and/or administration of fluids.[Ralston 2014] Traditionally, oxygen is given as dry gas through low-flow nasal prongs (LFNP). In the recent years a new method of oxygen supplementation has been used, delivering oxygen through heated humidified, high flow nasal cannula (HFNC). From retrospective studies and descriptive case series it is hypothesized that HFNC leads to better relieve of dyspnoea symptoms, less need for invasive respiratory support and less discomfort. [Hutchings 2015] However no solid evidence for the effect of HFNC has been shown from randomized controlled trials.[Cochrane 2014, Haq 2014] Bronchiolitis is an illness for which there are very limited proven treatment options. To establish HFNC as an effective and safe intervention in bronchiolitis has significant clinical implications. This intervention may provide an effective form of respiratory support that is less invasive and potentially has lower costs and fewer adverse events than conventional non-invasive ventilation therapy.
Several authors, including Cochrane reviewers emphasize the importance and urgent need for randomized controlled trials on this subject. [Cochrane 2014, Korppi 2016]

Study objective

To evaluate the effect on severity of dyspnoea of administration of oxygen through High Flow Nasal Cannula compared to oxygen delivery through Low Flow Nasal Prongs in children hospitalized for bronchiolitis with moderate to severe dyspnoea.

Study design

Multi Centre, Randomized controlled trial comparing oxygen supplementation via High Flow Nasal Cannula with oxygen supplementation via Low Flow Nasal Prongs.

Intervention

Standard mode of oxygen delivery (in the control group) is through dry gas at a limited flow rate < 2 L/min using nasal prongs. Higher flow rates of dry gas through nasal prongs are experienced as painful and uncomfortable air streams. The intervention in our study is the use of High Flow Nasal Canula to deliver oxygen to included patients. Through heating (to body temperature) and humidification (>99% relative humidity) of oxygen and air mixtures, comfortable oxygen delivery is allowed at flow rates matching or exceeding the patient*s inspiratory flow rate, thus limiting entrainment of room air.

Study burden and risks

Both intervention require the placement of nasal canula*s or prongs, which may

cause some inconvenience or discomfort to the child. Potential risks of High Flow may be abdominal distension, infections from the heated humidifying system or pneumothorax. However these risks are estimated to be very low and the use of High Flow has been supposed to be safe till so far. Patients are not exposed to any burden related to the collection of data; no extra blood samples or invasive measurements are performed. Since bronchiolitis is an age specific disease, occurring only - by definition - in children < 2 years of age, this study cannot be done in elder pediatric patients, nor in adults.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Patients < 2 years of age, hospitalised for bronchiolitis, with need for oxygensupplementation and moderate to severe dyspnoea.

Exclusion criteria

Bronchopulmonary dysplasia
Congenital heart disease
Congenital pulmonary abnormalities
Syndromal disease (for example trisomie 21)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2016
Enrollment:	118
Type:	Actual

Medical products/devices used

Generic name:	High Flow Nasal Cannula therapy
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	10-11-2016
Application type:	First submission

Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	12-12-2016
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	13-02-2018
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
Other	clinical trial.gov, nummer volgt
CCMO	NL56959.075.16