High Flow Nasal Cannula therapy in childhood asthma

Published: 14-01-2021
Last updated: 15-05-2024

To establish that recovery time from a bronchoprofocation test is faster with HFNC compared to no interfention

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Interventional

Summary

ID

NL-OMON54214

Source
ToetsingOnline

Brief title
High Flow Nasal Cannula therapy in childhood asthma

Condition

- Bronchial disorders (excl neoplasms)

Synonym
Asthma, shortness of breath

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Asthma, Children, HFNC

Outcome measures

Primary outcome

Recovery time after bronchoprovocation test, measured using spirometry.

Secondary outcome

1. Recovery time after the bronchoprovocationtest, measured using diaphragmatic

EMG

2. The relation between the pressures that the HFNC device produces to create

the applied flow and the recovery of lungfunction after the brochoprovocation

test

3. The relation between the shape of scaled tidal flow-volume curves and the

recovery of lungfunction after the brochoprovocation test.

Study description

Background summary

To establish wether a frequently used form of ariway therapy (HFNC) is suitable for childhood asthma

Study objective

To establish that recovery time from a bronchoprofocation test is faster with HFNC compared to no interfention

Study design

a randomized prospective cross-over trial

Intervention

High Flow Nasal Cannula therapy

Study burden and risks

The burden for the participants is an extra hospital visit with one additional bronchoprovocation test. The risk of this extra test is negligable.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

lungfunction liability >30% after bronchoprovocation test

Exclusion criteria

unable to perform spirometry

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-01-2023
Enrollment:	14
Type:	Actual

Medical products/devices used

Generic name:	Optiflow; Mobi-6 physiological amplifier
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	14-01-2021
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	03-05-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	23-11-2022

Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	18-04-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 20724
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL75416.100.20
OMON	NL-OMON20724