Nasal high flow in patients with exacerbation COPD and/or pneumonia on the lungward

Published: 04-11-2019
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The aim of this study is to determine if the use of Nasal high flow in patients with exacerbation COPD and/of pneumonia gives more comfort and a faster recovery then regular oxygen therapy

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Lower respiratory tract disorders (excl obstruction and infection)
Study type	Interventional

Summary

ID

NL-OMON54519

Source
ToetsingOnline

Brief title
Nasal high flow in patients witch COPD and/of pneumonia

Condition

- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
COPD, pneumonia

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W,Fisher and Paykel Healthcare Limited

Intervention

Keyword: comfort, COPD, Nasal high flow, pneumonia

Outcome measures

Primary outcome

Primaire parameter is comfort. we ask patients to complete CCQ daily during admittion.

Secondary outcome

Besides the primaire parameter, there will also measurements to investigate cough, dyspnea, oxygenation, respiration, heartfrequency, viscocity of the mucus and duration of admittion

Study description

Background summary

Patients admitted on the lungward have different lungproblems, with oxgenation problems as the result. This is treated with oxygen therapy. There are several methods of administration oxygen. Most commonly used is a tube under the nostrils applying oxygen. The Nasal high flow is also used for a numbre of years now, but only with patients with higher oxygen needs. This application has multiple benefits. Eg: heated and humidified oxygen and a higher flow

Study objective

The aim of this study is to determine if the use of Nasal high flow in patients with exacerbation COPD and/of pneumonia gives more comfort and a faster recovery then regular oxygen therapy

Study design

This is a randomized intervention study. Patients are randomized into 2 groups. Patients in the intervention group receive oxygen therapy by the nasal high flow. The control gropu receive oxygen by the regular oxygen application.

Intervention

Nasal high flow oxygen therapy

Study burden and risks

Patients are asked to complete different questionaires daily. These questionnaires are not burdensome. Patients in the intervention group use oxygen by nasal high flow. This is safely used in other wards and other patients on the lungward. This application is safe and there is no additional risk.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

exacerbation COPD and/or pneumonia
admitted on the lung ward
using oxygen, no less than 1 litre/minute

Exclusion criteria

acute hypercapnia or acidosis,
pneumothorax
delirium
domestic use of Bi-pap or C-pap

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-12-2019
Enrollment:	210
Type:	Actual

Medical products/devices used

Generic name:	Airvo(Nasal high flow)
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO Date:	04-11-2019
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	17-03-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	01-09-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	18-04-2024
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

No registrations found.

In other registers

Register	ID
CCMO	NL71035.100.19