# High Flow Nasal Oxygen Therapy re-evaluated from a conceptual point of view: Effect on Respiratory Effort and Lung Aeration after Extubation

Published: 29-08-2022
Last updated: 14-12-2024

Determine the physiological effect of HFNO compared to COT in the extubation phase regarding respiratory effort and lung aeration.

| | |
|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Completed |
| **Health condition type** | Respiratory disorders NEC |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON53601

**Source**
ToetsingOnline

**Brief title**
T-REX: Effect of HFNO Therapy on Respiratory Effort after Extubation

### Condition

- Respiratory disorders NEC

**Synonym**
respiratory failure, respiratory support

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam
**Source(s) of monetary or material Support:** Fisher & Paykel Healthcare

## Intervention

**Keyword:** High-flow nasal oxygen, Post-extubation, Respiratory effort

## Outcome measures

### Primary outcome

The main outcome is the difference in change in lung respiratory muscle effort (mean ΔPES) at 24 hours post-extubation between the study groups.

### Secondary outcome

Secondary parameters are differences in changes in respiratory effort at 2 and 4 hours post-extubation, difference in change in lung aeration (mean ΔEELI), differences in tidal volume, Lung Ultrasound (LUS) score, dyspnea score, and respiratory and sputum parameters between patients undergoing different post-extubation oxygenation regimens.

# Study description

### Background summary

Despite the lack of clear clinical protocols, High Flow Nasal Oxygen (HFNO) is used as post-extubation respiratory support. Although HFNO seems to reduce the need for re-intubation, scepticism on its use persists as the mechanism of action in post-extubation patients remains undefined. Monitoring weaning from invasive mechanical ventilation while monitoring respiratory effort might help to determine the added value of HFNO surrounding extubation. We hypothesize that HFNO, compared to conventional oxygen therapy (COT), prevents de-recruitment of the lung and reduces respiratory effort, and so provides a physiologic clarification for the reduction in the need for reintubation.

### Study objective

Determine the physiological effect of HFNO compared to COT in the extubation phase regarding respiratory effort and lung aeration.

### Study design

A physiologic, randomized clinical study comparing two standard of clinical care therapies.

### Intervention

Before extubation, patients are randomized to receive conventional oxygen (reference group) or HFNO as oxygenation regimen after extubation.
Both groups will undergo several minimally invasive measurements surroundig extubation, such as EIT, PES and Lung ultrasound score (LUS).

### Study burden and risks

Respiratory effort will be monitored according to routine clinical protocols by employing esophageal manometry, which is a minimally invasive and safe procedure. During the post-extubation phase, patients will undergo several additional non-invasive measurements. Risks associated with participation are expected to be negligible as all measurements and all treatment regimens are considered as standard of clinical care, and will now be applied as part of a structured study protocol. Study results are expected to be relevant for all patients weaning form IMV.

## Contacts

**Public**
Erasmus MC, Universitair Medisch Centrum Rotterdam

Doctor Molewaterplein 40
Rotterdam 3015GD
NL
**Scientific**
Erasmus MC, Universitair Medisch Centrum Rotterdam

Doctor Molewaterplein 40
Rotterdam 3015GD
NL

## Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

- Aged >= 18 years
- Receiving invasive mechanical ventilation >48 hours for any cause
- Scheduled for extubation as per local clinical guideline
- Provided informed consent

## Exclusion criteria

- Any clinical situation preventing appropriate execution of study procedures, such as;
o Severe agitated delirium
o Do not reintubate order
- The presence of a tracheostomy
- Respiratory acidosis, defined as a pH <7.32 with hypercapnia (PCO2 >6.5 kPa / PCO2 > 50 mmHg) during or after SBT
- Any feature that prohibits HFNO-initiation
o Recent facial upper-airway surgery
o Anatomic abnormalities that preclude appropriate fitting of HFNO cannula
o Current exacerbation of obstructive pulmonary disease
- Obstructive/central Sleep Apnoea Syndrome or Obesity Hypoventilation Syndrome in medical history
- Contra-indication for nasogastric tube or inability to perform adequate PES measurements, e.g.:
o Recent esophageal surgery
o Prior esophagectomy
o Known presence of esophageal varices
o Severe bleeding disorders
- Known diaphragm paralysis defined as elevated hemi-diaphragm on X-ray or evidence of paralysis during ultrasound (i.e. paradoxal diaphragm movement during sniffing)

- Known pregnancy or current breast-feeding

# 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: | Completed |
| Start date (anticipated): | 19-01-2023 |
| Enrollment: | 54 |
| Type: | Actual |

# Ethics review

| | |
|---|---|
| Approved WMO Date: | 29-08-2022 |
| Application type: | First submission |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 14-03-2023 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |

# 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 | NL80844.078.22 |