REspiratory Support in COPD after acUte Exacerbation.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25398

Source
Nationaal Trial Register

Brief title
RESCUE

Health condition

1. COPD;

2. Acute respiratory failure;

3. Non-invasive ventilation.

Sponsors and support

Primary sponsor: University Medical Center Groningen (UMCG), Department of Pulmonology
Source(s) of monetary or material Support: Astma Fonds
Respironics
Commissie Doelmatigheidsonderzoek

Intervention

Outcome measures

Primary outcome

Time to event is the primary study outcome, for which an event is defined as a readmission to hospital due to an exacerbation or death.

Secondary outcome

1. Exacerbations;

2. Health related quality of life;

3. Total readmission rate;

4. Total event rate;

5. Survival;

6. Medical costs;

7. Dyspnoea;

8. Activities of daily living;

9. Exercise tolerance;

10. Blood gasses PaO2 and PaCo2;

11. Lung function;

12. Inflammation (systemic) markers*;

13. Muscle strength*;

14. Nutritional status*;

* if possible in specialised centres.

Study description

Background summary

Rationale: Currently, chronic ventilatory support for patients with neuromuscular disease and

kyphoscoliosis in the Netherlands is routinely managed by 4 home mechanical ventilation (HMV) centres. In contrast, there is no consensus yet how to treat patients with COPD with chronic respiratory failure after an acute event, due to the lack of studies in this area. However, some patients in the Netherlands do receive chronic non invasive ventilation (NIV) after an acute event, while no evidence is available about its effect in the Netherlands or elsewhere. This is the reason why we want to investigate if chronic nocturnal NIV at home is effective in unstable patients with COPD, who remain hypercapnic after ventilatory support during acute respiratory failure.

Objective: The objective of this study is to investigate if chronic nocturnal ventilatory support at home after acute respiratory failure treated by ventilatory support either invasively or non-invasively leads to a prolongation in time to readmission to hospital for an acute exacerbation, improves quality of life, survival and cost-effectiveness in these patients compared to medical treatment only.

Study design: The protocol concerns a multi-centre, prospective, randomized, controlled study.

Study population: The study will be done in patients with Chronic Obstructive Pulmonary Disease (COPD) who remain hypercapnic after an exacerbation with acute respiratory failure treated in hospital by ventilatory support either invasively or non-invasively.
Intervention: It will take 2 years to include all 200 patients from which 100 will receive non-invasive ventilatory support at night at home as well as medical treatment, and 100 comprise the control group who will receive medical treatment only, for the duration of 1 year.

Main study parameters/endpoints: Primary study parameter: time to readmission. Secondary parameters; health related quality of life, readmission rate, survival, medical costs, dyspnoea, ADL, exercise tolerance, blood gasses, lung function, muscle strength, nutritional status.

Study objective

Does chronic nocturnal ventilatory support at home after acute respiratory failure treated by (N)IV lead to a prolongation in time to readmission to hospital due to any following exacerbations in these patients compared to medical treatment only.

Study design

Baseline, 3, 6 and 12 months.

Intervention

The intervention group will receive non-invasive ventilatory support at night at home as well as medical treatment, and the control group will receive standard medical treatment only for the duration of 1 year.

Contacts

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Eligibility criteria

Inclusion criteria

1. Chronic Obstructive pulmonary disease (COPD), GOLD severity stage 3 and 4;

2. Minimally 48 hours without ventilatory support after invasive or non invasive ventilatory support during an acute respiratory failure and maximally until discharge;

3. Persistent hypercapnia ($PaCO_2$ > 6.0 kPa) during daytime at rest without ventilatory support.

Exclusion criteria

1. Age < 18 or =>75 years;

2. Significant bronchiectasis with recurrent infections;

3. Significant heart failure;

4. Kyphoscoliosis;

5. Neuromuscular disease;

6) Obstructive sleep apnea (Apnea Hypopnea Index: AHI >15 /hr);

7. Current use of Continuous Positive Airway Pressure (CPAP) or Bilevel Positive Airway Pressure (BiPAP);

8. Insufficient motivation for chronic ventilatory support;

9. Social circumstances making chronic ventilatory support impossible;

10. Other disease factors limiting life expectations.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2007
Enrollment:	200
Type:	Actual

Ethics review

Positive opinion

Date:	25-09-2007
Application type:	First submission

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
NTR-new	NL1067
NTR-old	NTR1100
Other	: 2007/160
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A