REspiratory Support in COPD after acUte Exacerbation.

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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.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25398

Bron
Nationaal Trial Register

Verkorte titel
RESCUE

Aandoening

1. COPD;

2. Acute respiratory failure;

3. Non-invasive ventilation.

Ondersteuning

Primaire sponsor: University Medical Center Groningen (UMCG), Department of Pulmonology
Overige ondersteuning: Astma Fonds
Respironics
Commissie Doelmatigheidsonderzoek

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

Baseline, 3, 6 and 12 months.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen

(Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel

Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-11-2007
Aantal proefpersonen:	200
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	25-09-2007
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1067
NTR-old	NTR1100
Ander register	: 2007/160
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A