Diaphragm paralysis; surgery or mechanical ventilation?

Gepubliceerd: 05-08-2021 Laatst bijgewerkt: 18-08-2022

Primary question is whether the intended cost effectiveness / cost utility study is feasible. The study is feasible if at least 50% of the participants fulfilling the inclusion criteria are randomized in this pilot study.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24116

Bron
NTR

Verkorte titel
PARASOL

Aandoening

20 participants >18 year and diagnosed with a unilateral of bilateral diaphragm paralysis resulting from phrenic nerve injury.

Ondersteuning

Primaire sponsor: ZonMw
Overige ondersteuning: ZonMw dossiernummer 80-87700-98-22188

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary question of the pilot study is whether a randomized trial comparing surgery

versus non-invasive ventilation is feasible. In our opinion a randomized study is feasible if at least 50% of the participants fulfilling the inclusions criteria are randomized in this pilot study.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: The diaphragm is a dome-shaped muscle which separates the thoracic cavity from the abdomen. In patients with diaphragm paralysis the treatment (surgery versus non-invasive ventilation) is based on physician preference, not sound scientific evidence. Clearly studies are needed to guide a scientific decision making.
Objective: In this pilot study we will evaluate if patients are willing and able to participate in a randomized trial. Secondly this pilot study is also needed to know the clinical relevant effect of both therapies on EQ-5D_5L, the latter being the primary outcome. Finally, it will show us the costs of both therapies form a societal perspective.
Study design: open label, multi center randomized controlled trial
Study population: 20 participants >18 year and diagnosed with a unilateral of bilateral diaphragm paralysis resulting from phrenic nerve injury.
Intervention: 10 participants for surgical plication and 10 participants for nocturnal non-invasive ventilation.
Main study parameters/endpoints: The primary question of the pilot study is whether a randomized trial comparing surgery versus non-invasive ventilation is feasible. In our opinion a randomized study is feasible if at least 50% of the participants fulfilling the inclusions criteria are randomized in this pilot study.
The second goal of the pilot study is to describe the effect of both plication and NIV on the . primary endpoint being quality of life measured by the EQ-5D-5L questionnaire. Secondary endpoints are; the Medical Research Council (MRC) dyspnoea scale, the Diaphragmatic Paralysis Questionnaire, Borg dyspnoea score, Endurance Shuttle Walk Test (ESWT), spirometry in both sitting and supine position, a polysomnography an ergometry and transcutaneous measurement of carbon dioxide an oxygen saturation at night.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: after randomization the participants receives a treatment that was not the primary reason for referral which might be a barrier in participant recruitment. At the first outpatient visit a physical exam and an arterial blood gas analysis is performed. At baseline and 6 months after starting the therapy, quality of life questionnaires, an endurance shuttle walk test (ESWT), spirometry, ergometry, a polysomnography and transcutaneous monitoring of carbon dioxide an oxygen saturation at night will be performed. All these measurements are non-invasive and some are part of standard care.
Both treatments, non-invasive ventilation and surgical plication are considered as standard care, so participating in this study does not impose additional risks.

Doel van het onderzoek

Primary question is whether the intended cost effectiveness / cost utility study is feasible. The study is feasible if at least 50% of the participants fulfilling the inclusion criteria are randomized in this pilot study.

Onderzoeksopzet

At baseline and 6 months after starting the therapy: Quality of life measured by the EQ-5D-5L, the Medical Research Council (MRC) dyspnoea scale, the Diaphragmatic Paralysis Questionnaire, Borg dyspnoea score, Endurance Shuttle Walk Test (ESWT), spirometry in both sitting and supine position, a polysomnography an ergometry and transcutaneous measurement of carbon dioxide an oxygen saturation at night.
At two months a video call.

Onderzoeksproduct en/of interventie

Intervention: Surgical diaphragm-plication
Comparator: Non-invasive mechanical ventilation

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a participant must meet all of the following

criteria:
• >18 years
• diagnosed with a unilateral or bilateral diaphragm paralysis based on isolated phrenic nerve injury.
o Unilateral or bilateral diaphragm paralysis is defined as follows: complaints of dyspnea and / or orthopnea combined with a drop in VC of more than 15% when change from upright to supine position and a positive sniff test during fluoroscopy or ultrasonography. A positive sniff test means that the diaphragm stands still or even moves in cranial direction (paradoxical movement) during the sniff inspiratory maneuver.
• Ability to provide written consent
• Time between diagnosis and treatment should be at least 1 year

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study:
• Patients diagnosed with a unilateral or bilateral diaphragm paralysis due to a more systemic neurological or neuromuscular disorder like for example Amyotrophic Lateral Sclerosis ,
• Hypercapnia during daytime ($PaCO_2$ > 6.0 kPa)
• Radiotherapy of the thorax
• Contra indication for diaphragm surgery.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2022

Aantal proefpersonen:	20
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	05-08-2021
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	NL9705
Ander register	UMCG research register : 202100559 / ABR NL 78661.042.21 : METc UMCG 2021.484

Resultaten