Diaphragm paralysis; surgery or mechanical ventilation?

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24116

Source
NTR

Brief title
PARASOL

Health condition

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

Sponsors and support

Primary sponsor: ZonMw
Source(s) of monetary or material Support: ZonMw dossiernummer 80-87700-98-22188

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

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 and transcutaneous measurement of carbon dioxide an oxygen saturation at night.

Study description

Background summary

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.

Study objective

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.

Study design

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.

Intervention

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

Contacts

Public
UMCG
Anda Hazenberg

0503613200
Scientific
UMCG
Anda Hazenberg

0503613200

Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2022
Enrollment:	20

Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion Date:	05-08-2021
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	NL9705
Other	UMCG research register : 202100559 / ABR NL 78661.042.21 : METc UMCG 2021.484

Study results