Surgical Thoracic Outlet decompression versus conservative approach for Patients with Neurogenic Thoracic Outlet Syndrome, a randomized controlled trial (STOPNTOS)

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Spinal cord and nerve root disorders
Study type	Interventional

Summary

ID

NL-OMON46623

Source
ToetsingOnline

Brief title
STOPNTOS

Condition

- Spinal cord and nerve root disorders
- Nervous system, skull and spine therapeutic procedures

Synonym
Costo-Clavicular Compression Syndrome (CCCS), thoracic outlet syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: Catharina Onderzoeksfonds

Intervention

Keyword: DECOMPRESSION, NTOS, PHYSIOTHERAPY, RCT

Outcome measures

Primary outcome

Primary endpoint will be the DASH SCORE. This endpoint will be measured with

the DASH questionnaire (Disability of the Arm, Shoulder and Hand)

Secondary outcome

Secondary endpoint will be the score on the CBSQ, VAS scale and SF 12.

This endpoint will be measured with the CBSQ questionnaire (Cervical-Brachial

Symptoms Questionnaire), VAS scale (Visual Analogue Scale for Pain) and SF 12

(Short Form 12 questionnaire)

Study description

Background summary

Neurogenic thoracic outlet syndrome (NTOS) is a condition caused by compression and irritation of the brachial plexus serving the upper extremity. NTOS most frequently occurs in relatively young, active and otherwise healthy individuals and can have a tremendous impact on work, social and personal life. The diagnosis and therapy of NTOS still remains disputed. This is partly because diagnosis is largely clinical and subjective in nature, with no definitive (diagnostic) imaging or diagnostic studies available. As a result, disparities in the definition have produced different opinions regarding diagnostic standards for TOS.[1, 2] Furthermore, given the controversy surrounding the definition and diagnosis of TOS, conflict exists regarding the optimal treatment approach for this condition.
Studies in the last years, have shed light on some of the controversies in diagnosing and treating NTOS. Many patients that benefit from thoracic outlet

decompression (TOD) do not fit the historical diagnostic criteria [3, 4] Those patients (up to 90%) with disputed NTOS have shown improvement of symptoms and functionality after TOD surgery. [5-8]
Recently, several studies have been published about outcome after TOD surgery for NTOS. These large, multicentre studies clearly show a very low complication rate ranging from 0-2%, with an extremely low risk of nerve injury. [5, 9-13]

These studies however report on heterogenous populations, diagnosed without any internationally validated diagnostic criteria. They hint beneficial results for TOD in NTOS patients, however the level of evidence they provide is low. Critics have wondered if the improvements - reported in these trials - are attributed to surgery, or are merely due to coincidence, selection bias, conservative treatment or time (rest).

The society of vascular surgery published reporting standards in 2016 to produce consistency in diagnosis, description of treatment and assessment of results to allow more valuable data to be reported.[7] We believe that a randomized controlled trial - using the reporting standards- could demonstrate the actual added value of a TOD (first rib resection with partial scalenectomy and neurolysis).

Study objective

The objective of this study is to determine the value of TOD (first rib resection with partial scalenectomy and neurolysis) on functionality and quality of life. We will do this by randomizing patients into who already received physiotherapy into TOD or continued conservative physiotherapy. If patients in the conservative group still have complaints after 3 months, TOD will be offered and performed as well.
First, we will examine the effect of TOD versus physiotherapy on functionality and quality of life. We will look if there is a relation between the moment TOD and a change in functionality and quality of life. We will also determine the durability of the effect of TOD on functional assessment and quality of life (follow-up period of 5 years).

Study design

Single center randomized controlled trial

Intervention

Patients with a diagnosis of NTOS will be randomized into TOD versus conservative treatment. The group with conservative treatmentwill receive surgical therapy after 3 months if complaints persist.

Study burden and risks

All patients are operated with the same technique and by the same operator. There is a delay of 3 months for half of the subjects (except those patients who experienced such amount of relieve of their complaints under continuing physical therapy - these patients will not be operated of course), which is relative due to the early operation (in comparison with the existing waiting list) of the group that is randomised for direct TOD. There is no denial of *optimal medical treatment* for any of the participating subjects.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* High suspicion of NTOS with high level of impairment.
o The decision to refer a patient with NTOS for surgery is placed at the sole authority of the TOS multidisciplinary workgroup. Members of this workgroup are 2 dedicated vascular surgeons, 2 neurologists, 1 orthopedic surgeon, 3 physiotherapists, 2 radiologists, 3 anesthesiologists.
This decision is based on the reporting standards published by Illig et al. in 2016. If a patient fits the criteria postulated in the reporting standards, if the clinical suspicion is high, if the technical imaging (X-Ray, EMG, CT) is consistent, if the impairment for the patient is high and if there is consensus, only then patients are referred for TOD.
* Fit for surgery, at the discretion of the treating vascular surgeon and anesthesiologist.
* 18 years of age or older
* Dutch speaking patients

Exclusion criteria

* Unfit for surgery, at the discretion of the treating vascular surgeon.
* Younger than 18 years of age
* Patients that do not speak Dutch or English.
* Patients with a history of TOD

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:	Recruiting
Start date (anticipated):	01-10-2018
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	04-06-2018
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	12-09-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL63986.100.17