Neuralgic amyotrophy: Central reorganization and rehabilitation after peripheral dysfunction

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Primary Objectives: * To determine if NA patients have altered cerebral activity related to motor planning of their affected arm compared to healthy controls and compared to their non-affected arm.* To determine if specific rehabilitation focused on...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Peripheral neuropathies
Study type	Interventional

Summary

ID

NL-OMON44371

Source
ToetsingOnline

Brief title
NA-CONTROL

Condition

- Peripheral neuropathies

Synonym
Neuralgic amyotrophy; Parsonage□Turner syndrome; Brachial Neuritis

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Prinses Beatrix Spierfonds

Intervention

Keyword: clinical trial, neuralgic amyotrophy, neuroimaging, rehabilitation

Outcome measures

Primary outcome

For the cross-sectional comparison, as well as for the neuroimaging part of the randomized controlled trial, the main parameters are changes/differences in the magnitudes of mean functional MRI signal (BOLD activity) related to motor imagery of the affected arm, quantifying changes in central motor control.

For the clinical part of the randomized controlled trial, the main parameter is change in functional (dis)ability of the shoulder, arm and hand, measured with the Shoulder Rating Questionnaire (SRQ), after a 17-week treatment period.

Secondary outcome

Secondary study parameters include:

Both for the cross-sectional comparisson and the randomized controlled trial :

Differences/changes in:

- behavioral performance (i.e. reaction times and error rates) on 2 motor imagery tasks (which require participants to imagine making arm/hand movements, assessing cognitive motor control)
- functional and structural organization of the brain (as assessed with MRI neuroimaging techniques)
- reachable workspace, as measured with a standardized movementprotocol and Kinect sensor

- scapular position and orientation when lifting the arm, as derrived from 3D-photography
- maximum force exerted with the serratus anterior (when reaching with elbow, and with hand), endo- and exorotation of shoulder, key grip, and hand grip
-fatigue, as measured with the checklist individual strength - subscale fatigue
-quality of life, as measured with the short form 36

Only for the randomized controlled trial:
Differences/changes in:
-functional disability of the arm shoulder and hand as measured with the Disability of Arm, Shoulder and Hand.
-pain, as measured with the McGill Pain Questionnaire
-self-efficacy for performing energy conservation strategies, as measured with the Self-Efficacy for Performing Energy Conservation Strategies Assessment
-pain self-efficacy, as measured with the Pain Self-Efficacy Questionnaire
-participation, as measured with the Utrecht Scale for Evaluation of Rehabilitation-Participation
-patients' activation with regard to their health and disease, as measured with the Patient Activation Measure

-changes (pre- and post-experimental intervention) in occupational performance and satisfaction with performance of the most important daily occupations identified as a problem by the patient. This is assessed with the Canadian

Occupational Performance Measure.

Study description

Background summary

Neuralgic amyotrophy(NA) is a common (incidence 1:1000) peripheral nervous system disorder caused by acute autoimmune inflammation of the brachial plexus. Many NA patients develop abnormal motor control of the scapular region, scapular dyskinesia, which persists even after peripheral nerve recovery. This suggests that persistent scapular dyskinesia in NA may result from (mal)adaptive changes in the cerebral motor system. Rehabilitation focused on cognitive motor control can restore scapular dyskinesia, indicating that the impaired motor control can be restored. This leads to the novel concept that peripheral nerve damage may lead to central adaptations that are compensatory in the acute phase, but lead to impaired motor control in the chronic phase. We hypothesize that NA is associated with maladaptive cerebral motor control, resulting in scapular dyskinesia. Rehabilitation focused on cognitive motor control can reverse these cerebral changes and is more effective in improving functional disability than usual care.

Study objective

Primary Objectives:
* To determine if NA patients have altered cerebral activity related to motor planning of their affected arm compared to healthy controls and compared to their non-affected arm.
* To determine if specific rehabilitation focused on cognitive motor control can reverse the central changes in NA patients, and improves functional disability in NA, as compared to usual care.
Secondary Objective(s):
* To determine if central changes in NA patients* cognitive networks can be detected with functional MRI and structural MRI.
* To evaluate whether specific rehabilitation results in improvements in a wide range of domains, including scapular dyskinesia and personal factors such as fatigue, participation and quality of life.
* To assess lasting effects of treatment (17 weeks post treatment) on a variety of factors, including functional ability, participation, quality of life, personal factors and patient activation.

Study design

Exploratory cross-sectional comparison and open-label randomized controlled

trial.

Intervention

25 NA patients will receive a 17-week specific and personalised rehabilitation program. The program starts with a visit to the Plexuspoli in week 1. During this visit, the patient will be examined by a multidisciplinary team, consisting of a rehabilitation physician, neurologist, physical therapist and occupational therapist, which will form a rehabilitation treatment plan. This treatment plan is implemented through4 weekly sessions in week 2*5, 2 biweekly sessions in week 6*9 and 2 monthly sessions in week 10*17. Each treatment session involves one hour of physical- and one hour of occupational therapy.

25 NA patients will first continue their usual care, which varies for each individual (including no treatment), for 17 weeks, after which they will also receive the 17-week specific rehabilitation program at the Radboudumc.

Study burden and risks

Healthy controls will undergo a single assessment (± 3.5 hours). Both the intervention and usual care groups will undergo a pre- and post-treatment assessment (± 4.5 hours each). The group initially receiving usual care, will undergo a third assessment after receiving the intervention. Each assessment includes an Magnetic Resonance Imaging (MRI) experiment (±1 hour), muscle strength measurements, a motor imagery behavioural task, recordings of scapular dyskinesia, and several questionnaires. In a 17-week post-intervention follow-up, both groups will fill out several questionnaires from home. Experience gained in pilot studies and the out-patient clinic indicates that patients can complete the rehabilitation program, lay down in an MRI-environment, perform scapular and strength assessments and the proposed motor imagery tasks. We therefore believe that both the treatment and assessments pose little to no discomfort to participants. NA patients will likely benefit greatly from participating in the specific rehabilitation program.

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

General:
1. Aged * 18 years
2. Right-handed
3. Able to provide informed consent;Neuralgic amyotrophy (NA) patients:
1. Diagnosis of NA
2. NA predominantly present in the right upper extremity
3. In subacute or chronic phase of NA (i.e. no inflammation of plexus, >2-3 months after attack onset)
4. Presence of scapular dyskinesia

Exclusion criteria

General:
1. Pregnancy
2. Severe comorbidity
3. A history of or recent surgery, biomechanical constraints and/or periarticular fractures of the arm/shoulder
4. Any other neuromusculair disease affecting the shoulder girdle
5. Any central nervous system disorder, neurological disorder (e.g. Parkinson, cerebrovasculair accident, etc.)
For undergoing MRI experiment:

6. Presence of an active implant and/or any non-removable metal parts in or on the upper body
7. Claustrophobia
8. Epilepsy ;NA patients
1. (Prior) NA attacks of the left upper extremity or lumbosacral plexus
2. Patients in the acute phase of NA (characterized by severe pain and inflammation of the brachial plexus)

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:	Recruitment stopped
Start date (anticipated):	04-01-2018
Enrollment:	75
Type:	Actual

Ethics review

Approved WMO

Date:	11-01-2018
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL63327.091.17