Quantification of muscular fatty degeneration in brachial plexus injury patients

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The purpose of this study is: 1) to develop a method to quantify muscular fat content in brachial plexus injury patients;2) to investigate whether muscular fat content is more in the affected arm compared to the contralateral arm in BPI patients;3)...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neuromuscular disorders
Study type	Observational non invasive

Summary

ID

NL-OMON35089

Source
ToetsingOnline

Brief title
Muscular fatty degeneration

Condition

- Neuromuscular disorders

Synonym
Brachial plexus injury, injury of the nerves innervating the arm

Research involving
Human

Sponsors and support

Primary sponsor: Orthopaedie
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Brachial, Fat, Muscle, Plexus

Outcome measures

Primary outcome

The primary study parameters are:

1) the percentage of muscular fat in the musculus biceps brachii and triceps

of the affected and contralateral arm.

2) The Goutallier grading will be used to compare qualitatively grading method

with the quantifative grading method of muscular fat content.

The m. biceps brachii and triceps of the contralateral non affected arm will be

used as a control muscles.

Secondary outcome

Secondary study parameters are:

1) elbow flexion and extension range of motion and strength

2) quality of life questionnaire: SF36 and DASH

Study description

Background summary

A brachial plexus injury (BPI) is the most severe nerve injury of the extremities and the majority of these patients have residual muscle weakness. To improve the utility of their arm, they need nerve and/or secondary surgery. Long-term denervation results in muscle atrophy, fatty degeneration and interstitial fibrosis of the muscle. Quantitative tools which assess muscular fat content could improve insight in the extent of muscle degeneration and could facilitate a better treatment strategy. In previous studies, the three-point Dixon MRI has been used to measure muscular fat content in lean and obese children. Furthermore the three-point Dixon MRI has been used as a marker

of muscle weakness in children with Duchenne Muscular Dystrophy.

Study objective

The purpose of this study is:
1) to develop a method to quantify muscular fat content in brachial plexus injury patients;
2) to investigate whether muscular fat content is more in the affected arm compared to the contralateral arm in BPI patients;
3) to evaluate differences in muscular fat content between patient groups with insufficient recovery and with sufficient recovery of muscle function.

Study design

A comparative pilot study will be performed to quantify differences in muscular fat content by three-point Dixon MRI between two groups of BPI patients. The first group will include patients with insufficient recovery of the m. biceps brachii (MRC 0-3) who underwent Steindler flexorplasty to improve their elbow flexion. The second group will include patients with sufficient recovery of their m. biceps brachii (MRC 4) who did not need secondary surgery to improve elbow flexion. An MRI will be performed of both upper arms, together with fysical examination and two quality of life questionnaires.

Study burden and risks

Potential risks are considered minimal because this is a non invasive study. In patients with a Steindler flexorplasty, could observe some warming of the screw in the distal humeral bone. However, this risc is considered minimal because the screw is MRI compatible (pure titanium). While the patients participating in this study may not directly derive any immediate benefits, the results of the study should improve methods to quantify muscle weakness in brachial plexus injury patients.

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

Brachial plexus injury diagnosed by orthopaedic surgeon or neurosurgeon.
Patiënts have to be in end stage of neural regeneration i.e. at least 2 years after trauma or nerve surgery

Exclusion criteria

Bilateral brachial plexus injury.
Not 3 tesla MRI eligible due to any reason.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-08-2010
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO

Date:	24-06-2010
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL31766.058.10