A pilot study of elbow stiffness as a possible measure for axonal misrouting in obstetric brachial plexus lesions

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The objective of this study is to measure the stiffness of the elbow as a measure for axonal misrouting. This method can later aid physicians in determining whether to use botulinum A or not in OBPL.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Congenital and peripartum neurological conditions
Study type	Observational non invasive

Summary

ID

NL-OMON36163

Source
ToetsingOnline

Brief title
Elbow stiffness as a measure of misrouting in OBPL

Condition

- Congenital and peripartum neurological conditions

Synonym
Erb's palsy, OBPL

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: axonal misrouting, joint manipulator

Outcome measures

Primary outcome

Stiffness of the elbow joint as a measure for axonal misrouting.

Secondary outcome

Not applicable.

Study description

Background summary

Obstetric Brachial Plexus Lesion (OBPL) is a closed traction injury of the nerves of the arm acquired during birth. Functional regeneration in OBPL is much more complex than a peripheral nerve injury in an adult. In infants as in adults, recovery depends on the number of outgrowing axons, but two factors complicate matters in infants: these are 'misrouting' and the response of an immature brain that is still developing motor programmes. If the 'tubes' surrounding the axons are disrupted, an outgrowing axon does not necessarily end up in the intended tube. If it does not, the sprouting axon can end up in the wrong muscle, even one with an antagonistic function. The problem is compounded when the sprouting axons form multiple branches that may end up in completely different muscles. This so-called misrouting can explain co-contractions, in which shoulder abduction and elbow flexion, or elbow flexion and extension become irreversibly linked.
To facilitate the formation of central motor programmes co-contraction due to misrouting of the triceps during arm flexion can temporarily be eliminated by injecting botulinum toxin type A in the triceps. Botulinum A is believed to have effect but the lack of prospective, randomized controlled trials shows that botulinum A treatment for children with OBPL is still at an experimental stage. A systematic literature review has shown that there is no consensus yet on the exact indication criteria or outcome measures for application of botulinum A. In order to perform such a trial, a method for the measurement of the amount of misrouting should be defined.
We have previously assessed successfully motor misrouting in a group of eighteen adult OBPL subjects after comparing them to sixteen controls. The method used was based on the principle that misrouting can be assessed by electrically stimulating any branch of a neuron which will excite all its

branches. This method was primarily aimed at understanding the branching patterns of misrouting, not at its mechanical consequences. The aim of this study is to evaluate elbow stiffness as a new method measuring the mechanical constraints as a result of misrouting in OBPL.

Study objective

The objective of this study is to measure the stiffness of the elbow as a measure for axonal misrouting. This method can later aid physicians in determining whether to use botulinum A or not in OBPL.

Study design

Pilot study which compares a group of OBPL patients with a control group. The subjects are requested to hold the handle of a joint manipulator which applies small movements on the handle. An EMG is recorded of their biceps and triceps muscle in that arm which enables the measurement of the stiffness of the elbow which can be used as a measure for axonal misrouting.

Study burden and risks

No risk is expected. The burden consists of the 1 - 1,5 hour duration of the investigation.

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

Patients:
Obstetric brachial plexus lesion

Exclusion criteria

Patients and controls:
Disorders affecting neuronal and muscular control other than OBPL.
Patients:
Neurosurgical reconstruction

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	23-02-2012
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	30-01-2012
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	NL35694.058.11