

Sensation in children with an Obstetric Brachial Plexus Palsy

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

Summary

ID

NL-OMON40623

Source

ToetsingOnline

Brief title

Sensation OBPL

Condition

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

Synonym

Erbs palsy; birth brachial plexus lesion

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Research Fonds Neurochirurgie LUMC

Intervention

Keyword: Birth injury, Brachial Plexus, Sensation

Outcome measures

Primary outcome

1 Sensation

The sensation of the hand will be assessed using the following methods.

1.1 Semmes-Weinstein Monofilamenttest

Nylon filaments of different size provide a reproducible pressure on the skin, which allows for assessing the quality of the sensation buds in the skin.

1.2 Two-point discrimination

The minimal distance that children recognize two contact points as two separate stimuli is investigated, which reflects the density of the sensation buds

1.3 Stereognosis: object recognition

The child must recognize an object with touch alone, without seeing it.

1.4 Localisation test

The largest Semmes-Weinstein monofilament is placed on a specific finger of the hand, the child must name on which finger the filament is pressed.

1.5 Beside the previous objective tests of sensation, a questionnaire is taken to assess the subjective sensation of the hand, and pain sensation in the hand.

Secondary outcome

2 Hand function

Hand function will be assessed as follows

2.1 Grip strength will be quantified using a Jamar dynamometer.

2.2 Handiness will be evaluated with a single item from the Movement Assessment Battery for Children-2 (MABC-2), which is an internationally accepted and validated test for fine motor skills.

2.3 A questionnaire is employed to determine the function of the hand in daily living activities.

3 Other motor functions (not in control group)

The assessment of motor function of shoulder and elbow movements is part of 'usual care*' at the outpatient clinic. Range of motion and strength is evaluated by experienced investigators of the NerveCenter of the LUMC. This part of data is necessary to document the severity of the nerve lesion and to be able to correlate with outcomes of sensation and hand function.

Study description

Background summary

The obstetric brachial plexus lesion (OBPL) is a traction injury that occurs during birth. The most common type is a lesion of the two upper nerves of the brachial plexus, which are C5 and C6. It is a clinical observation, that was acknowledged in a number of clinical papers, that - despite a good motor recovery of the C5 and C6 spinal nerves - a certain clumsiness of the hand was noticed. This is remarkable, because motor innervation of the hand is innervated by the three lower nerves of the brachial plexus, i.e C7, C8 en T1, which should not be involved in a C5-C6 lesion.

One explanation for this observation is that hand function was diminished by diminished sensation of the hand. The spinal nerve C6 serves the palmar surface and finger tips of the thumb and index finger, and thus diminished sensation in this area probably exists in C5-C6 lesions. The diminished sensation is the subject of the current research proposition.

From a therapeutical point of view it is important to have proper knowledge of

the sensation function of children with an upper brachial plexus lesion, as treatment regimes might be adapted to improve sensation. Current literature does not contain a good description of sensation in children with an OBPL.

A first shortcoming is that a validated measurement tool for sensation in children is lacking. We performed a literature research on existing measurement tools to develop a method that is applicable in children. The set of found methods or tools were adapted for the intended population to suit practicality (smaller size of children's fingers), understanding and concentration. These modifications were tested as pilot in a number of healthy children, which led to further adaptations. The resulting measurement tool will be employed during this study.

Study objective

The main objective is to investigate if the sensation of children with an upper OBPL is diminished. Both children that were treated conservatively as children that were surgically treated with nerve surgery in early infancy.

The primary research question is:

1. Do children with an upper OBPL have a normal sensation of the hand ?

To answer this question sensation will be measured in a control group of healthy children without nerve lesion.

Secondary research questions are:

2. What is a good measurement tool to assess sensation of the hand in children; which parts of the measurement tool are sensitive clinical practice to diagnose a diminished sensation.

3. Is there a correlation between sensation of the hand with clinical parameters, like motor recovery of the limb, severity of the nerve lesion, and hand function.

The hypothesis is, that sensation of the hand is diminished in children with an upper OBPL, which could potentially explain clumsiness of the hand.

Study design

The study design is a cross sectional investigation of patients that are followed in our patient clinic of the NerveCenter of the LUMC.

To answer the primary research question our measurement tool will be employed to assess sensation in 50 children with an upper OBPL. Depending on the results of the first 20 children, intra- and inter-observer variability will be investigated.

In a control group of 25 healthy children our measurement tool will be applied.

The secondary research questions will be investigated with the obtained results.

Study burden and risks

The age of the population is 7 up to 12 years .

The investigation is not invasive or painful, but they demand attention and cooperation.

The measurement of sensation shall be done by an experienced child physiotherapist, on a child friendly way.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Children (2-11 years)

Inclusion criteria

- Children who suffered an obstetric brachial plexus lesion (OBPL) involving the C5 and C6 spinal nerves regardless whether they were treated with nerve surgery or conservatively
- These children are under treatment or follow-up at our outpatient brachial plexus clinic
- Children's age 7 to 12 years
- Children who are in regular primary school

Exclusion criteria

- Children who cannot follow instructions
- Children without sufficient motivation

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:	Diagnostic

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	05-11-2014
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO	
Date:	07-10-2014
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO

Date: 10-12-2014

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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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	NL48977.058.14