Clinical analysis of upper extremity movements in children with Obstetric Brachial Plexus Lesion

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*Evaluate our current measurement procedure (*UX analysis report*), that objectively and accurately records the 3D movement of the UX, in healthy children to establish norm values, normal variation and reproducibility in children*Test whether the UX...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON30621

Source
ToetsingOnline

Brief title
UpEx

Condition

- Other condition
- Movement disorders (incl parkinsonism)

Synonym
nerve damage, Obstetric Brachial Plexus Lesion

Health condition

Obstetric Brachial Plexus Lesion (OBPL)

Research involving
Human

Sponsors and support

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

Intervention

Keyword: ADL, kinematics, OBPL, upper extremity

Outcome measures

Primary outcome

*3D kinematics and variation and specific parameters which can only be

determined after the study with the patients is completed. Then we can detect

where the 3D kinematics of the patients differ from the healthy population and

translate this into specific parameters.

Secondary outcome

not applicable

Study description

Background summary

The VUmc is one of the three centers of excellence in the Netherlands on offering specialized multidisciplinary treatment for children with Obstetric Brachial Plexus Lesion. In severe cases a plexus recontruction will be done a few months after birth (primary surgery). When a child reaches the age of four and the functional use of the affected arm is still limited, secondary surgery will be considered, such as muscle and tendon transfers.
The decision to perform a certain surgical procedure is currently mainly based on the clinical expertise and experience of the surgeon and physiatrists. However, current clinical assessment methods are insufficient to predict and evaluate optimal treatment. Joint ROM (Range of Motion) and qualitative observation of activities, are not sufficient to describe actual (dys)function and are unable to distinguish between primary (loss of muscle control and/or power) and secondary (compensatory movements) consequences of the disease. Therefore, to evaluate functional effects and make it accessible for further research, there is a need for an objective, quantitative method, which includes

intersegmental coordination and the analysis of these motions in 3D. In a pilot study we developed a measurement protocol for the kinematic evaluation of the upper extremities (UX) of healthy adults. The aim of the current study is to develop and apply this measurement protocol for kinematic evaluation of the UX of healthy children and children with OBPL.

Study objective

*Evaluate our current measurement procedure (*UX analysis report*), that objectively and accurately records the 3D movement of the UX, in healthy children to establish norm values, normal variation and reproducibility in children
*Test whether the UX analysis report adequately distinguishes UX movement in pre-operative OBPL children compared to the norm values
*Test whether shifts from pre- to postoperative values can be distinguished by the UX analysis report as moving towards norm values

Study design

Observational study to compare groups:
*Cross-sectional: OBPL children with indication for secondary surgery compared to healthy children
*Longitudinal: OBPL patients before and after secondary surgery

Study burden and risks

The extensive kinematic data of the UX movements that will be collected, will give a better quantitative understanding of movement deviations as opposed to regular clinical examination. In the future, this additional data is expected to lead to better diagnosis and treatment. The development of gait analysis has been extremely useful in the treatment of lower extremity dysfunctions. Likewise, analysis of UX functions by means of 3D kinematics has the potential to become an important tool in clinical decision-making and therapeutic evaluation of patients with UX disorders.
The additional risks of the current study for the subjects are negligible and the burdens minimal. The measurements are non-invasive. Subjects will be sitting on a stool with movement sensors attached to their upper bodies. Most patients will be familiar with the movements because many of these are standard in clinical examinations. The kinematic movement sensors and the straps that will be used to attach them, will be a new situation for the children, as well as the fact that they will be connected to the computer with a cable that is necessary for data collection. From our gait analysis experience, it is known that children comply with this measurement technique. Parents/guardians and children will be informed about the measurement procedures and tools beforehand so that they will be prepared for this, and that they will know about any possible burdens.

We believe the benefits clearly outweigh the risks or burdens for the subjects.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Patients:
Clinical diagnosis of Obstetric Plexus Brachial Lesion
Age: between 4 and 12 years of age
male and female;Healthy controls:
age: 4-7 and 8-12 years
male and female

Exclusion criteria

Patients:
- Additional disorders (other than OPBL) that influence the child's movement pattern of the upper extremities
- Parents or guardians and child do not understand the Dutch or English language well enough to take part in this project;Healthy controls:
- Any (known) deviation that may influence movements of the upper extremities
- Parents or guardians and child do not understand the Dutch or English language well enough to take part in this project

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:	Pending
Start date (anticipated):	01-01-2007
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL12553.029.06