Ultrasound of the brachial plexus in obstetric brachial plexus injury. Feasibility study in healthy neonates

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The aim of this study is to visualize the cervical roots and brachial plexus in neonates reliably and reproducable.

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

Summary

ID

NL-OMON35378

Source
ToetsingOnline

Brief title
US of the brachial plexus

Condition

- Congenital and peripartum neurological conditions

Synonym
erb's palsy

Research involving
Human

Sponsors and support

Primary sponsor: Canisius Wilhelmina Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Brachial plexus, obstetric, Ultrasound

Outcome measures

Primary outcome

Ultrasound appearance of

1. Nerve roots: C4 to T1 nerve roots will be visualized longitudinally to evaluate continuity with the spinal cord and aspect of the nerves and surrounding tissue.

2. Brachial plexus: The brachial plexus will be visualized transverse at 3 levels: cervical, supraclavicular and infraclavicula. Continuity, aspect of the nerve and surrounding tissue, visibility of internal structures, and cross-sectional area will be evaluated.

3. Peripheral nerves: Transverse images of the medial nerve at the wrist and ulnar nerve just ditally from the elbow will be made to evaluate the diameter, cross sectional area and visibility of internal structures.

4. Muscle ultrasound of C4 to T1 innervated muscles (measurement of muscle echo intensity and muscle thickness):

a. Infraspinatus (C4-C6)

b. Deltoid (C5-C6)

c. Biceps brachii (C5-C6)

d. Triceps (C6-C8)

e. Extensor digitorum communis (C6-C8)

f. Flexor digitorum superficialis (C7-C8)

g. Adductor digitorum brevis (C8-T1)

Secondary outcome

n.a.

Study description

Background summary

Ultrasound of the brachial plexus in obstetric brachial plexus injury: feasibility study in healthy neonates.

Background
The incidence of obstetric brachial plexus injury (OBPI) is 1.6 to 2.9 /1000 neonates. It is the most common peripheral nerve injury in children.
Studies on the long term outcome of OBPI vary between studies, but a large population study showed that approximately 25% of all children with OBPI suffer from reduction in arm function because of paresis of upper arm, fore arm or hand muscles, contractures and growth disorders of the affected arm.
In case of severe nerve damage without signs of improvement in the first month, especially of the biceps brachii muscle, surgical intervention is indicated. It is difficult to estimate early which children are going to need surgery, as both reversible nerve damage (neuropraxis and axonotmesis) as well as irreversible nerve damage (neurotmesis, root avulsion) show the smae clinical picture in the first weeks. Electrophysiological studies did show significant differences between children with an unfavourable outcome compared to those with a good outcome, but it was impossible to determine a cut-off point with high enough predictive values to be used in clincial practice. Currently, referral to a neurosurgical expertise centre (LUMC in Leiden, Atrium MC in Heerlen and VU in Amsterdam) is done at 3 months of age, with surgical intervention around 6 months of age.
Early intervention, when indicated, would be desirable, as the brain has its highest plasticity in the first months of life. Therefore, it would plausible the early surgical intervention would improve functional outcome. However, there are no clinical or electrophysiological parameters yet to determine the long term outcome reliably before the age of 3 months.

With improvement of ultrasound technology it has become possible to visualize the aspect and continuity of peripheral nerves with high resolution. As ultrasound can be used bedside and without sedation even in the very young, it is a very useful diagnostic tool in children. Nerve ultrasound is currently primarily used in the diagnosis of compression neuropathies, such as carpal tunnel syndrome, but new applications are evolving rapidly. Recent studies have

showed that also the brachial plexus can be visualized with ultrasound. This technique is used for ultrasound guided regional anesthesia. Studies on the use of this technique in traumatic brachial plexus injury are limited to one study in which was showed that root avulsion could be predicted right in 9 out of 12 patients, in 2 patients nerve damage was underestimated. This would indicate that the predictive value of nerve ultrasound in brachial plexus injury is higher than MRI or CT.

Study objective

The aim of this study is to visualize the cervical roots and brachial plexus in neonates reliably and reproducable.

Study design

Inclusion criteria:
20 Neonates with a gestational age of at least 32 weeks. Inclusion occurs in the first week of life.

Exclusion criteria:
- Symptoms or signs suspect for a neurological disoder (brain haemorrhage or infarction, periferal nerve damage, neuromuscular disorder)
- Fracture of clavicula or humerus
- Family history of peripheral neuropathy

Measurements setting
The measurements will be performed at the maternity ward or neonatology department.

Equipment:
Ultrasound images will be made with a Philips IU22 ultrasound device with a linear broadband 7-15 MHz probe with a small footprint ("hockeystick probe").

Measurements (bilaterally):
1. Nerve roots: C4 to T1 nerve roots will be visualized longitudinally to evaluate continuity with the spinal cord and aspect of the nerves and surrounding tissue.
2. Brachial plexus: The brachial plexus will be visualized transverse at 3 levels: cervical, supraclavicular and infraclavicula. Continuity, aspect of the nerve and surrounding tissue, visibility of internal structures, and cross-sectional area will be evaluated.
3. Peripheral nerves: Transverse images of the medial nerve at the wrist and ulnar nerve just ditally from the elbow will be made to evaluate the diameter, cross sectional area and visibility of internal structures.
4. Muscle ultrasound of C4 to T1 innervated muscles (measurement of muscle echo intensity and muscle thickness):

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b. Deltoid (C5-C6)
c. Biceps brachii (C5-C6)
d. Triceps (C6-C8)
e. Extensor digitorum communis (C6-C8)
f. Flexor digitorum superficialis (C7-C8)
g. Adductor digitorum brevis (C8-T1)

The final protocol will be determined based on the first 5 measurements. The feasibility study will be performed in 20 neonates.

Study burden and risks

There are no risks or burden associated with participation in this study

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Healthy neonates above 32 weeks gestational age in the first week of life

Exclusion criteria

Family history of neuromuscular disease, shoulder dystocia

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):	22-04-2012
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	17-02-2012
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	NL38418.091.11