A possible prevention of Obstetric Brachial Plexus Lesion (OBPL)

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Ethical review	Not approved
Status	Will not start
Health condition type	Congenital and peripartum neurological conditions
Study type	Interventional

Summary

ID

NL-OMON34822

Source
ToetsingOnline

Brief title
Prevention 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: nerve stimulation, OBPL

Outcome measures

Primary outcome

The possibility of stimulating the n. accesorius and making the shoulders shrug

by nerve stimulation in babies.

Secondary outcome

Used strength of the current.

Study description

Background summary

Shoulder dystocia is a severe complication during labour which means that the child's shoulder gets stuck in the birth canal. This can be a traumatic experience for the parents but it can also have serious consequences for the child itself. Shoulder dystocia is the biggest risk factor for obstetric brachial plexus lesion (OBPL). OBPL means that due to the difficult passage of the shoulders during labour, the network of nerves on each side of the neck leading to the arm can be damaged. In healthy subjects this connection between the brains and the arm is responsible for the movement of various muscles and the sensibility in different skin parts. These functions can be damaged in varying gradaients in OBPL. When recovery of the nerves is unsufficient, the development of essential muscles will fail such as bending of the elbow by the biceps, which is necessary for everyday tasks as feeding, combing hair etc. OBPL occurs in 1-3 per 1000 newborns from which 20 - 30 % keep permanent damage. Nowadays the neurosurgeon can operate on the most severe cases, but even then recovery of the arm function is less than can be observed on the healthy side.

Study objective

In this investigation we want to determine if stimulation of the nerve on each side of the neck that leads to the muscles that make the shoudlers shrug is possible in babies. This can possibly prevent a birth lesion of the barchial plexus in the future (also called obstetric brachial plexus lesion -OBPL- or

Erbs palsy).

Study design

The investigation takes about half an hour. An experienced clinical neurophysiologist determines the location for electrical stimulation of the accessory nerve in the neck. In the first phase stimuli are applied to see if the nerve reacts and then a train of stimuli is applied to see if the shoulders stay shrugged. So two trains of stimuli are applied, each of which is half to one second long, starting with a strength of the current as determined with adults. The effect of nerve stimulation on the distance between the shoulders is evaluated by the investigator and is also recorded on video.

Intervention

Stimulating n. accesorius, which leads to the m. trapezius which shrugs the shoulders and which is positioned on both sides of the neck close under the skin.

Study burden and risks

Stimuli can be perceived as unpleasant, but are very safe due to the many years of experience in children. We do not expect severe stimuli. When the load is higher than expected, the legal representative can at any time withdraw the child from participation. The time load is at most half an hour. Two stimuli trains are applied where each stimulus is a half to one second, starting with the low current strength as determined in adults and not experienced as painful.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

children, preferably younger than one month

Exclusion criteria

present injury to the arm (nerves, muscles), central nervous system damage;
children not older than three months

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	10
Type:	Anticipated

Ethics review

Not approved

Date:	21-02-2011
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	NL31834.000.10