

The influence of physiotherapy on the shoulder function of children with Obstetric Brachial Plexus Injury (OBPL).

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23122

Source

Nationaal Trial Register

Brief title

OBPL, Erb's palsy

Health condition

Shoulder function children OBPL, obstetric brachial plexus injury, Erb's palsy
Schouderfunctie kinderen OPBL, obstetrisch plexus brachialis letsel, Ebse parese

Sponsors and support

Primary sponsor: Atrium Medical Centre Heerlen

Source(s) of monetary or material Support: Stichting ter Behartiging der Belangen van het Gebrekkige Kind, Valkenburg

Intervention

Outcome measures

Primary outcome

Results on functional level of the shoulder:

1. Mallet Score (active shoulder function): 5 items (scores: II-IV);
2. Range of Motion (ROM, passive shoulder function): 7 items (degrees).

Results on activity level of the shoulder:

1. ABILHAND-children: 21 items (scores: impossible, difficult, easy).

Secondary outcome

Same as the primary. The only difference is that the execution of shoulder related sports is included as physiotherapy minutes. The distribution of the participants in the above mentioned groups will change and probably also the outcomes.
The classification of the two groups will be the same.

Study description

Background summary

A cross-sectional study will be executed by which a group children with OBPL who received frequently physiotherapy will be compared with a group of children with OBPL who received less frequent physiotherapy.

The results of both groups will be compared on shoulder mobility, arm-hand function and arm-hand ability.

The frequency and duration of the physiotherapy, the executed sports and measured Mallet scores in the past will be collected by retrospective research.

Both Belgium and Dutch children with OBPL are invited. Belgium children receive in general more often physiotherapy than Dutch children. For reaching sufficient participants in both classification groups it is important to have participants with much and less physiotherapy.

Study objective

The expectation is that children with OBPL who received more physiotherapy have a better shoulder function than children with OBPL with less received physiotherapy.

Study design

One measure moment at present for the Mallet score, the ROM and the ABILHAND-Kids.

Previously measured ROM and Mallet scores.

Intervention

Classification of two groups:

1. High frequent physiotherapy group:

Children with OBPL who received weekly ≥ 60 minutes of physiotherapy during their life;

2. Low frequent physiotherapie group:

Children with OBPL who received weekly < 60 minutes of phsyiotherapy during their life.

Contacts

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Eligibility criteria

Inclusion criteria

1. Children with OBPL who have C5-6 or C5-C6-C7 lesions;
2. Age group: 1994-2006;
3. Children which received this lesion at birth;
4. Children with OBPL from the Netherlands and Belgium.

Exclusion criteria

1. Children with OBPL which also have C8 and/or Th1 lesions besides above mentioned lesions;
2. Low level of development. The child should be able to understand and execute the instructions;
3. The parents of the children younger than 12 years old have to understand the Dutch language.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-05-2011
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion	
Date:	04-05-2011
Application type:	First submission

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
NTR-new	NL2746
NTR-old	NTR2884
Other	METC Heerlen : 11-N-18
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A