Obstetrical brachial plexus lesion: a pilot study of outcome and general functioning in adults.

Published: 24-06-2011
Last updated: 27-04-2024

To increase to knowledge of how adults with OBPL function, this research will be done with de next researchquestion: what iare the lengterm consequences of OBPL among adults? These questions are being adressed to with fhe ICF structure:- body...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone disorders (excl congenital and fractures)
Study type	Observational non invasive

Summary

ID

NL-OMON36402

Source
ToetsingOnline

Brief title
OBPL: a pilot study of outcome and general functioning in adults.

Condition

- Bone disorders (excl congenital and fractures)
- Congenital and peripartum neurological conditions

Synonym
erb's palsy, obstetrical brachial plexus lesion

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: adults, general outcome/pain, obstetrical brachial plexus lesion, shoulderfunction

Outcome measures

Primary outcome

DASH

Secondary outcome

X-ray anterioposterior and axial; right and left shoulder

Passive range of motion test of the upper extremity

Active range of motion test of the upper extremity

Handheld dynomometry / Yamar dynamometer

sensitivity 2-pointdiscrimination

Scoliosis investagion (sitting)

Armlength left and right (cm)

Circumference of the arm, left and right (cm)

VAS scores

Modified Mallet-score

ARA-test

NHP-test

MOS-SF 36

Study description

Background summary

Obstetric brachial plexus lesion (OBPL) occurs at birth. There has been done a lot of research on how to treat children. During childhood mild constraints in

daily life are being seen as well as occurence of pain and glenohumeral deformities. There has been very little research to the effects of OBPL to adults. Adults with OBPL are hardly being seen by physiatrists. Therefore little is known about adults with OBPL among physiastrists. The fact that adults with OBPL are hardly seen can have multiple explanations. It is possible that there are little to no contstraints. It is also possible that patients don't know there way to the physiatrist.

Study objective

To increase to knowledge of how adults with OBPL function, this research will be done with de next researchquestion: what iare the lengterm consequences of OBPL among adults?
These questions are being adressed to with fhe ICF structure:
- body structure & function: how is the anatomy of the affected side compared to the healthy side? Is osteoarthrosis more common on the affected shoulder? How is the passive range of motion (PROM) and the active range of motion (AROM) of both shoulders? How is the strength on the affected side? Are there big differences between the different lesion levels? How frequent and to what extend does pain occur? Which body part endures the most pain?
- Activity and Participation: are there constraints in activities of daily life? What is the influence of OBPL on daily life functioning: work, household, freetime?
- Is there a relation between shoulderfunction/shoulderpain and functioning in activiaty and participation?

Study design

In this cross-sectional pilot study the ICF will be used: body structure & function and activity & participation. The instruments that will be used are physicial examination, x-rays, functionality testing and questionnaires. If possible the affected side will be compared to the healthy side. Other tests will be compared to healthy numbers. The entire research will take place in 2,5 year time.

Study burden and risks

A time investment of 3,5 hours is asked. In this period a questionaire had te be filled in and a visit to the VUMC will be made. During this visit a thorough physical examination will take place and there will be 4 x-rays made, 2 of each shoulder. The risks that come with the x-rays are minimal.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

The inclusion criteria are adults with unilateral OPBL, aged 18-65 years, able to speak Dutch or English.

Exclusion criteria

The exclusion criteria are double sided OPBL and central neurological comorbidity.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-02-2012
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	24-06-2011
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	NL34036.029.11