

# Daily activities, participation, quality of life, health care usage and satisfaction in patients with Obstetric Brachial Plexus Injuries

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The aim of the present study is: Primary objectives:1. To determine the health status of children and (young)adults with OBPI in terms of upper extremity function, daily activities, sports, participation and overall quality of life. 2. To determine...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON40968

### Source

ToetsingOnline

### Brief title

ZAP-Plexus

### Condition

- Other condition

### Synonym

Erb's paresis, Obstetric Brachial Plexus Injuries

### Health condition

Obstetrisch Plexus Brachialis Letsel

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Leids Universitair Medisch Centrum

**Source(s) of monetary or material Support:** Afdelingsbudget Orthopedie LUMC

## Intervention

**Keyword:** Care, OBPI, Participation, QoL

## Outcome measures

### Primary outcome

Socio-demographic status (age, gender, dexterity, education, work etc.),  
relevant disease specific questions (not present in existing questionnaires)  
regarding functional abilities, participation, the use of assistive devices,  
cosmetics, impact on family, health care utilization and satisfaction with  
care (OBPI GAP-C), Upper extremity functioning (ABILHAND-Kids, HUH, PODCI-NL,  
DASH-DLV and MHOQ-DLV), Quality of Life (TAPQOL, TACQOL, TAAQOL, DISABKIDS,  
SF-36), Physical Activity (SQUASH, AQUA), Participation (IPA, USER-P) and  
Transition from childhood into adulthood (Rotterdam Transition Profile).

### Secondary outcome

N.a.

## Study description

### Background summary

An Obstetric Brachial Plexus Injury (OBPI) occurs in about 0.4-4.6 per 100 live births. Nerve damage to the brachial plexus can cause problems in using the arm/hand even though primary and/or secondary surgery has been performed. Until now little is known about perceived problems in daily life activities, participation and quality of life in this patient group. The Leiden University

Medical Center (LUMC) is one of the 3 specialized OBPI centers in the Netherlands and a large part of all patients with OBPI are or were seen here in regard to their possible (functional) problems. This provides the opportunity to gather more insight into the perceived problems of this patient group. In regard to the health care usage and satisfaction about provided care, within specialized centers as well as in local health care centers, in the OBPI patient group knowledge is almost absent.

## **Study objective**

The aim of the present study is:

Primary objectives:

1. To determine the health status of children and (young)adults with OBPI in terms of upper extremity function, daily activities, sports, participation and overall quality of life.
2. To determine health care usage and satisfaction with current health care in patients with OBPI.
3. To investigate the relation between reported health status and the severity and localization of the brachial plexus injury, taking into account received medical treatment.

Secondary objectives:

4. To investigate the validity, reliability and usefulness of the Hand Use at Home (HUH) questionnaire in the paediatric OBPI population (2-10 years old).

## **Study design**

A cross sectional study will be performed by means of online or paper questionnaires.

Patients and/or parents/legal representatives of patients will be asked to fill out a number of questionnaires regarding the pre-mentioned domains once. To investigate the validity and reliability of the HUH, the parents of patients between the age of 2-10 years will be asked to fill out the HUH once again 2 weeks after the initial administration.

## **Study burden and risks**

This cross sectional study will be carried out among children (0-16 years) and (young)adults (>16 years) with an OBPI. All questionnaires will be filled out by parents/legal representatives or patients where appropriate. The time to complete all questionnaires is approximately 2 hours, except for the population between the ages of 0-2 years in which it will be approximately 30 minutes, and can be divided over different time points. The burden is minimal and no risks are associated with participation in this study. The study gathers information to gain more insight into health related Quality of Life, Arm function, Activities and Participation of this patient group. In combination with the

information gathered about healthcare utilization and satisfaction of care this provides valuable information to optimize care and patient information regarding OBPI. Additionally a newly developed questionnaire (the Hand Use at Home (HUH) questionnaire) is validated within the 2-10 year old patient group which provides more insight into hand functioning. Such a questionnaire is not available yet for the OBPI patient group.

## Contacts

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### **Age**

Adolescents (12-15 years)  
Adolescents (16-17 years)  
Adults (18-64 years)  
Children (2-11 years)  
Elderly (65 years and older)

### Inclusion criteria

Obstetric Brachial Plexus Injury

## Exclusion criteria

Unable to read and write in Dutch

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Health services research

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-09-2014

Enrollment: 1250

Type: Actual

## Ethics review

Approved WMO

Date: 12-05-2014

Application type: First submission

Review commission: METC Leids Universitair Medisch Centrum (Leiden)

## 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	NL48163.058.14