Evaluation of supination deformity in residual plexus brachialis injury

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

Summary

ID

NL-OMON38753

Source
ToetsingOnline

Brief title
SUPPLEX

Condition

- Congenital and peripartum neurological conditions

Synonym
Erb's paralysis, Shouder dystocia, Supination deformity

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: biceps rerouting, obstetric brachial plexus, osteotomy, Quality of life

Outcome measures

Primary outcome

The main study parameter is the elbow RoM of pronation and supination.

Secondary outcome

Secondary parameters are Malletscore, Raimundi score, shoulder RoM and biceps

strength, Tacqol Quality of life scoring.

MRI-scans will be evaluated for degree of atrophy and/or fatty degeneration.

Study description

Background summary

Rationale: Supination deformity is estimated to be present in 6-10 % of children with residual plexus brachialis birth injury. Several types of operative correction have been described in literature. In our hospital mid-distal radiusosteotomy and/or proximal ulna osteotomy have been performed in cases of supination contracture. For active pronation deficit without true contracture, Zancolli biceps rerouting was performed. In forearm osteotomies a recurrence rate as high as 20-40 % is reported in literature, possibly due to persistent supination forces and growth. In this project we will evaluate the longterm results and the potential (dis)advantages of forearm osteotomies and bicepsrerouting. Our hypothesis is that at follow-up, the Range of Motion (RoM) will be increased in all patients versus the pre-operative status.

Study objective

The primary goal of this study is to evaluate the clinical long term results of patients with a forearm osteotomy and/or soft-tissue procedures to correct a supination deformity. Furthermore we will try to identify association between functional outcome and age at intervention, preoperative malletscore and shoulder, elbow and hand function, in an attempt to be able to optimize selection of patients for operative procedures.
Secondary goals are to compare preoperative MRI muscle quality scores in patients with supination deformity compared to a matched patient group with

residual plexus injury without supination deformity.

Study design

Retrospective cohort study with historical patient groups: mid-distal radius osteotomy alone, ulna osteotomy alone, both bone forearm osteotomy and biceps rerouting. Control group of patients with a supination deformity who did not receive surgical intervention. Preoperative MRI scan of the elbow of these patients with supination deformity, compared to a Narakas classification and age matched control group of elbow MRI-scans of plexus brachialis patients without a supination deformity.

Study burden and risks

The potential risk associated with this study is negligible. Patients included in this study will reveive the same care as all other patients.

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

Patients with a supination deformity due to residual plexus brachial birth injury, for which they received a osteotomy or biceps rerouting between 1990 and 2012.

Exclusion criteria

* No informed consent
* Insufficient Dutch Language skills

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2014
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	02-10-2013
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

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	NL46145.058.13