Treatment of the elbow's flexion contractures in Neonatal Brachial Plexus Injury (NBPI): serial casting or dynamic orthosis? A comparison of interventions.

Published: 03-06-2013
Last updated: 24-04-2024

The ojective of the study is to answer the quenstion which of the following interventions is most effective in the treatment of children with a severe elbow flexion contracture with Neonatal Brachial Plexus Injury : static serial softcasting or...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON38634

Source
ToetsingOnline

Brief title
Elbow's flexion contractures in NBPI

Condition

- Joint disorders

Synonym
Flexion contractures, impossibility to extend the elbow

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: Brachial Plexus, Contractures, Dynamic Orthosis, Serial Casting

Outcome measures

Primary outcome

goniometrics in praxis and blinded goniometrics by measuring at a photo

constructed by a blinded therapist.

Secondary outcome

Goal Attainment Scaling with functional goals.

Study description

Background summary

The Elbow's flexion contractures in children with Neonatal Brachial Plexus Injury (NBPI) frequently occur. Treatment additively to stretching is required when there is progression of the contracture, a contracture of > 30 degrees, or recurrence after treatment.

Study objective

The ojective of the study is to answer the quenstion which of the following interventions is most effective in the treatment of children with a severe elbow flexion contracture with Neonatal Brachial Plexus Injury : static serial softcasting or treatment with the dynamic elbow orthesis?

Study design

prospective randomized single blinded study

Intervention

This study compares two usually applied inerventions. Intervention 1 concerns circular serial casting lasting 4 to 6 weeks with change of casts weekly. After serial casting a removable dorsal splint is used during the night. Intervention 2 concerns a dynamic orthosis with polypropyleen dorsal scales and an extension

Utraflex hinge. This orthosis is used during every night for one year.

Study burden and risks

None

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

1. Diagnosis NBPI
2. Age 2-18 y
3. Additive treatment indication.

Exclusion criteria

1. Insufficient parents' or child's capacity to understand the instructions regarding the use of the orthosis.
2. Insuffitient motivation.
3 A known caput radii dislocation.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2013
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	Orthosis and serial casting
Registration:	No

Ethics review

Approved WMO

Date:	03-06-2013
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	NL43722.058.13