The long-term effect of the babysitterprocedure after proximal nerve injury.

Published: 20-08-2008
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Aim of this study was to assess the long term effects of the babysitter procedure in patients with proximal nerve injury.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Muscle disorders
Study type	Observational non invasive

Summary

ID

NL-OMON31639

Source
ToetsingOnline

Brief title
The babysitterprocedure.

Condition

- Muscle disorders
- Peripheral neuropathies

Synonym
decrease of muscle mass following nerve injury, denervation atrophy

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Stichting NutsOhra

Intervention

Keyword: atrophy, nerve injury, sensory protection

Outcome measures

Primary outcome

Recovery of muscle strenght and muscle volume.

Secondary outcome

Recovery of sensibility, nerve conduction, contraction following stimulation of

the nerve.

Study description

Background summary

Proximal peripheral nerve injury often leads to poor functional recovery due to irreversible muscle atrophy, which has taken place before regenerating axons have reached the target muscle. Temporary innervation by a sensory nerve prevents denervation atrophy. This is also called the "babysitterprocedure"

Study objective

Aim of this study was to assess the long term effects of the babysitter procedure in patients with proximal nerve injury.

Study design

Results of patients who underwent the babysitterprocedure are compared to the results of patients without an additional operation (historical control group).

Study burden and risks

Not applicable.

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

Patients who underwent the babysitterprocedure following a total transection of the ulnar or median nerve, 10 cm or more proximally from wrist crease. Same patients without an additional operation.

Exclusion criteria

Anastomoses between the median and ulnar nerve, for example a Martin-Gruber anastomosis, anastomoses from the ulnar to the median nerve, palmar anastomoses.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2008
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	20-08-2008
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL19612.078.07