High resolution ultrasound imaging after complete median or ulnar nerve transection; a pilot study

Published: 08-09-2006
Last updated: 20-05-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON30100

Source
ToetsingOnline

Brief title
HR nerve US

Condition

- Other condition

Synonym
nerve transection

Health condition

perifeer zenuw letsel en chirurgisch herstel

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: follow-up, nerve repair, nerve transection, ultrasound imaging

Outcome measures

Primary outcome

Clinical, EMG and HR US parameters (see protocol for details) will be compared intraindividually over time using nonparametric correlation analysis. Furthermore, the HR US parameters will be compared intraindividually, both positionally (7 positions) and temporally (4 longitudinal measurements) within one arm and between two arms using repeated measures ANOVAs. To find out whether HR US parameters can be useful for the prediction of nerve regeneration, (logistic) regression analysis will be used.

Secondary outcome

nvt

Study description

Background summary

Currently, there is no easily accessible non-invasive technique available to visualize peripheral nerves. The existence of such a technique would be useful in diagnosing nerve transections and follow-up after nerve repair. After nerve repair sprouts will form and regenerating axons will grow into the distal stump. Besides a Tinel*s sign (distal tingling on percussion of the nerve), which is not always present, there are no clinical signs of regeneration until the axons reach the muscles or skin receptors. In practice this may last up to 12 months depending on the distance that needs to be bridged by the regenerating nerve, the type of nerve, the age of the patient and numerous

other factors. If function fails to return within the expected period, surgical exploration may be justified. Causes of failure of nerve regeneration may be a discontinuity of the nerve, obstruction by fibrosis or the formation of a neuroma. In these cases the patient would benefit from earlier exploration to resolve the cause and reestablish nerve function in an earlier phase.

Ultrasound scanning is a non-invasive imaging technique applied widely in medicine. A disadvantage compared to other imaging techniques is its low spatial resolution. Recently, a High Resolution (14MHz) Ultrasound (HR US) scanner has become available in our institution. Pilot tests showed that it is capable of displaying large nerves in healthy subjects in clear contrast to its environment. Using this technique the nerve diameter and circumference, and its aspect (density (grayness) and inhomogeneity) can be quantified. These parameters may be indicative for nerve regeneration and therefore HR US may be a useful technique to follow nerve regeneration after nerve repair in large nerves.

Study objective

The aim of our study is to investigate the value of HR US to visualize and quantify regeneration of transected median or ulnar nerves as a function of time after surgical nerve repair.

Study design

The present study will be of a prospective nature. Patients after complete median or ulnar nerve transection and repair will undergo HR US scanning examinations of the arm 1, 3, 6 and 12 months postoperatively. These additional HR US investigations will be scheduled on the same day as regular appointments in the outpatient clinic. HR US data will be correlated to clinical findings, moving and static 1-point and 2-point-discrimination and EMG data.

Study burden and risks

There are no adverse effects known of ultrasound investigations at 10-14 MHz. The concentric needle EMG is experienced as (mildly) unpleasant, depending on the muscle under investigation and can occasionally cause bruises. All other EMG investigations are not invasive and have no known adverse effects.

Although not likely, a nerve repair may fail. In those cases this will probably be visualized with HR US, and these subjects will be excluded from the study and sent to the treating plastic surgeon for further evaluation and treatment accordingly. Otherwise, the participation of patients in this study is of no influence on their treatment.

Further, no unexpected findings with clinical relevance are expected in this

investigation.

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

- complete median or ulnar nerve transection
- 18 years or older
- likely to complete follow-up

Exclusion criteria

- history of generalized polyneuropathy

- localized earlier pathology of transected nerve
- multiple nerve transections
- nerve transection <1 cm from the carpal tunnel

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-06-2007
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	08-09-2006
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL13971.042.06