

Decision for reconstructive interventions of the upper extremities in tetraplegia: the effect of treatment characteristics.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22006

Source

Nationaal Trial Register

Brief title

N/A

Health condition

Spinal cord injury.

Sponsors and support

Source(s) of monetary or material Support: The study is part of the research project "The upper extremity in spinal cord injury: natural course and preferences for restorative treatment" and belongs to the research programme "Physical strain, work capacity, and mechanisms of restoration of mobility in the rehabilitation of individuals with a spinal cord injury". For the research project and the research programme grants (nos. 014-32-026 and 96-06-004) were received from the Dutch Health Research and Development Council.

Intervention

Outcome measures

Primary outcome

Importance and the relative weight of 7 treatment characteristics on the decision to undergo reconstructive surgery.

Secondary outcome

N/A

Study description

Background summary

Objective:

To assess the effect of treatment characteristics on the decisions made by subjects with tetraplegia concerning reconstructive interventions for the upper extremities.

Design:

Survey.

Setting:

Seven specialized spinal cord injury centres in the Netherlands.

Patients:

A sample of 49 individuals with tetraplegia in a stable condition.

Interventions:

Not applicable.

Main outcome measure:

Importance and the relative weight of 7 treatment characteristics on the decision to undergo reconstructive surgery determined by means of Conjoint Analysis.

Results:

All 7 characteristics contributed to the decision to undergo surgery ($p < 0.01$). The relative weights were: for type of intervention 0.14 (95% confidence interval (CI) 0.05-0.23), for number of operations 0.15 (95% CI: 0.05-0.25), for inpatient rehabilitation period 0.22 (95% CI: 0.10-0.32), for outpatient rehabilitation period 0.08 (95% CI: 0.02-0.14), for risk of complications 0.16 (95% CI: 0.06-0.26), for results of elbow function 0.1 (95% CI: 0.02-0.18), and for results of hand function 0.15 (95% CI: 0.05-0.25). In 40.8% of the subjects one characteristic had a relative weight of 0.30 or more.

Conclusions:

Non-health outcome factors related to the intensity of treatment are as important or even more important than the potential outcome of hand or elbow function in the decision to undergo reconstructive therapy. Inpatient rehabilitation period was the most important factor, and a substantial number of subjects focus on only one characteristic in their decision-making process.

Study objective

None; study was a survey.

Study design

N/A

Intervention

None.

Contacts

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Eligibility criteria

Inclusion criteria

The inclusion criteria were a motor complete C5, C6 or C7 SCI, according to the guidelines of the American Spinal Injury Association (ASIA) , with at least one arm classified as motor group 1 to 4 according to the International Classification for Surgery of the Upper Limb in Tetraplegia. Subjects had to be medically and neurologically stable, at least one year after the initial injury, and possible candidates for surgical reconstruction of elbow extension and palmar and/or lateral grasp function.

Exclusion criteria

Subjects were excluded if they had previously undergone surgery to improve UE function, or if they had been extensively informed about these interventions and had declined treatment in the past 5 years.

Study design

Design

Study type: Interventional

Intervention model: Other

Control: N/A , unknown

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 05-09-2002

Enrollment: 53

Type: Actual

Ethics review

Positive opinion

Date: 06-09-2005

Application type: First submission

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
NTR-new	NL422
NTR-old	NTR462
Other	: nos. 014-32-026 and 96-06-004
ISRCTN	ISRCTN93725261

Study results

Summary results

Spinal Cord. 2008 Mar;46(3):228-33. Epub 2007 Aug 7.