

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

Submission date
26/02/2007

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
26/02/2007

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
26/08/2021

Condition category
Injury, Occupational Diseases, Poisoning

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

014-32-026 and 96-06-004, NL422 (NTR462)

Study information

Scientific Title

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

Study objectives

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

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from the Medisch Ethische Toetsingscommissie (Medical-ethical board) of Roesingh Rehabilitation Centre on the 27th February 2002 (ref: 02.08.7.2).

Primary study design

Observational

Study design

Survey

Study type(s)

Other

Health condition(s) or problem(s) studied

Spinal cord injury

Interventions

Seven specialised spinal cord injury centres in the Netherlands. 53 individuals with tetraplegia in a stable condition were surveyed on the importance and the relative weight of seven treatment characteristics:

1. Type of intervention
2. Number of operations
3. Inpatient rehabilitation period
4. Outpatient rehabilitation period
5. Risk of complications
6. Results of elbow function
7. Results of hand function

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

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

Key secondary outcome(s)

No secondary outcome measures

Completion date

01/02/2005

Eligibility

Key inclusion criteria

1. A motor complete C5, C6 or C7 Spinal Cord Injury (SCI), according to the guidelines of the American Spinal Injury Association (ASIA)
2. At least one arm classified as motor group one to four according to the International Classification for Surgery of the Upper Limb in Tetraplegia
3. Subjects had to be medically and neurologically stable
4. At least one year after the initial injury
5. Possible candidates for surgical reconstruction of elbow extension and palmar and/or lateral grasp function

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Total final enrolment

49

Key exclusion criteria

1. Previously undergone surgery to improve Upper Extremity (UE) function
2. Extensively informed about these interventions
3. Declined treatment in the past five years

Date of first enrolment

05/09/2002

Date of final enrolment

01/02/2005

Locations

Countries of recruitment

Netherlands

Study participating centre

Roessingh Research and Development B.V.
Enschede
Netherlands
7522 AH

Sponsor information

Organisation

Roessingh Research and Development B.V. (The Netherlands)

ROR

<https://ror.org/01dmjt679>

Funder(s)

Funder type

Research organisation

Funder Name

The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		07/08/2007	26/08/2021	Yes	No