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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

Registration date
26/02/2007

Overall study status
Completed

Last Edited
26/08/2021

Condition category
Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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).

Study design
Survey

Primary study design
Observational

Secondary study design
Multi-centre

Study setting(s)
Other

Study type(s)
Other

Participant information sheet

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

Secondary outcome measures
No secondary outcome measures

Overall study start date
05/09/2002

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
53

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
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Sponsor information

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

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Sponsor type
Industry

Website
http://www.rrd.nl/www/indexa.html

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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