Neurotraumatology Quality Registry

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24871

Source
Nationaal Trial Register

Brief title
Net-QuRe

Health condition

Traumatic Brain Injury
Traumatisch Hersenletsel

Sponsors and support

Primary sponsor: Rijndam Rehabilitaton and Leiden University Medical Center
Source(s) of monetary or material Support: Dutch Brain Foundation
Hersenstichting

Intervention

Outcome measures

Primary outcome

Glasgow Outcome Scale Extended
Health-related Quality of Life

Secondary outcome

Physical functioning, Cognitive functioning, Depression, Aphasia, Disease Awareness, Fatigue, Activities, Participation, Employment Outcome, Healthcare Consumption, Costs

Study description

Background summary

Many acute and post-acute interventions for traumatic brain injury (TBI) are not evidence-based. Clinical practice is often too complex to be studied in clinical trials. Strict in- and exclusion criteria and selected treatment settings result in limited external validity. Large between-institution variation in process and structure of treatment may remain unnoticed leading to suboptimal patient outcomes. Comparative effectiveness research (CER) is a promising alternative to investigate the effectiveness of treatments in clinical practice. CER depends on high quality observational data, which are currently lacking in the Netherlands. Therefore development of a quality registry is a prerequisite to open the black box of the acute and post-acute treatment variety for TBI.

Study objective

Based on a new Neurotraumatology Quality Registry, best practices can be identified in the health care chain for patients with moderate and severe TBI

Study design

Hospital admission, Hospital discharge, Rehabilitation admission, Rehabilitation discharge, 6 months, 12 months, 24 months

Intervention

NA

Contacts

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Eligibility criteria

Inclusion criteria

- Diagnosis of Traumatic Brain Injury
- GCS score < 13 at presentation at ER or =<24 hours after presentation at ER due to TBI
- Presentation at ER within 24 hours
- Age >= 16 years

Exclusion criteria

- Non-traumatic cause of reduced level of consciousness (cardiac or intoxication) at ER presentation
- Insufficient mastering of the Dutch or English language
- Serious (neurological) morbidity pre-injury which may interfere with TBI outcome

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2016

Enrollment:	1000
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	28-07-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 46984
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5761
NTR-old	NTR6003
CCMO	NL50366.058.14
OMON	NL-OMON46984

Study results