Comparative effectiveness research within the Dutch Neurotraumatology Quality Registry.

Published: 25-01-2019
Last updated: 12-04-2024

The objective of the study is to set up and validate a digital neurotraumatology quality registry, to identify the most effective clinical care and to provide high quality evidence in support of treatment recommendations and guidelines.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Increased intracranial pressure and hydrocephalus
Study type	Observational non invasive

Summary

ID

NL-OMON50369

Source
ToetsingOnline

Brief title
Net-QuRe

Condition

- Increased intracranial pressure and hydrocephalus
- Nervous system, skull and spine therapeutic procedures

Synonym
Head injury due to trauma

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Hersenstichting

Intervention

Keyword: brain, traumatic brain injury

Outcome measures

Primary outcome

Outcome measures will include functional outcome, social participation and

heath related quality of life.,

Secondary outcome

Same as primary parameters.

Study description

Background summary

There is a lot of discussion about the optimal treatment of traumatic acut subdural heamatoma and the intraparenchymal contusion in relation with timing of neurosurgical interventions. Treatments varies in regions and between practitioners. A comparative effectiveness study isn't done.

Study objective

The objective of the study is to set up and validate a digital neurotraumatology quality registry, to identify the most effective clinical care and to provide high quality evidence in support of treatment recommendations and guidelines.

Study design

Longitudinal prospective observational cohort study with a follow-up of 2 years. Comparative effectiveness research (CER) provides a promising framework to identify best practices and improve outcome after TBI.

Study burden and risks

There are no risks.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Presentation within 24 hours of injury.
Clinical diagnoses traumatic brain injury.
GCS < 13 by presentation ER.
Secundair decrease (GCS < 13) <= 24 hours after presentation on the ER.
Informed Consent obtained according to local and national requirements.
Age 16 year or older.

Exclusion criteria

Severe pre-existing neurological disorder that would confound outcome assessments.
By presentation a not traumatic cause of decreased consciousness.
Insufficient knowledge of Dutch or English language.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-02-2019
Enrollment:	1000
Type:	Actual

Ethics review

Approved WMO

Date:	25-01-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	30-04-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO Date:	24-06-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	20-10-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL65064.058.18