Early intensive neurorehabilitation in patients with Disorders of Consciousness: Treatment and Outcomes Registry (DOCTOR)

No registrations found.

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

Summary

ID

NL-OMON23779

Source
Nationaal Trial Register

Brief title
DOCTOR

Health condition

Acquired brain injury

Sponsors and support

Primary sponsor: Libra, rehabilitation & audiology
Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

The rate and timing of recovery of consciousness, using the Coma Recovery Scale-Revised.

Furthermore the number and type of medical complications, including pain and mortality, patient's level of disability, including the level of motor, cognitive, behavioural and emotional functioning, participation, and quality of life.

Secondary outcome

Secondary outcomes include self-efficacy of caregivers and caregivers' strain and cost-effectiveness of the program.

Study description

Background summary

Rationale: Disorders of consciousness (DOC) occur after severe brain injury from various aetiologies. The states of DOC are coma, vegetative state (VS) or unresponsive wakefulness syndrome (UWS), and minimally conscious state (MCS). The outcomes of DOC in patients receiving early intensive rehabilitation (EIN) have been studied and showed that half to two thirds of patients with DOC regained consciousness at discharge. Furthermore, better outcomes in self-care, mobility, and cognition, and less complications have been observed in patients with DOC during intensive neurorehabilitation. However, long-term outcomes of DOC after EIN have not been studied systematically. From January 2019, EIN is insured standard care for all patients in the Netherlands (formerly only persons until 25 years had access to the programme), which is concentrated at Libra Rehabilitation & Audiology.
Objective: The aim of this study is to set up a registry and to systematically study the long-term outcomes of patients with DOC who receive EIN.
Study design: Single-centre prospective cohort study with a 2-year follow-up period. Measurements take place at start EIN, in week 5, 10, and at discharge of the EIN programme (duration = max 14 weeks) and at week 28, 40, 52, and 104.
Study population: Patients with DOC due to acute brain injury who receive EIN, aged 16 years and older.
Intervention (if applicable): Not applicable.
Main study parameters/endpoints: The rate and timing of recovery of consciousness, using the Coma Recovery Scale-Revised, the number and type of medical complications, including pain and mortality, patient's level of disability, including the level of motor, cognitive, behavioural and emotional functioning, participation, and quality of life. Secondary outcomes include self-efficacy of caregivers and caregivers' strain and cost-effectiveness of the program.

Study objective

Systematically study the long-term (2-years) outcomes of patients with DOC who receive EIN

Study design

5 years

Intervention

none

Contacts

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Eligibility criteria

Inclusion criteria

• Age16 years or older.
• DOC (UWS or MCS) lasting > 2 weeks at admission and < 6 months
• First-time newly acquired non-progressive brain injury of any aetiology confirmed by neurological and /or neuroimaging data
• Weaned from ventilator
• Medically stable, as judged by the treating rehabilitation physician.

Exclusion criteria

• Coma
• Any pre-existent progressive or non-progressive brain injury
• Uncontrollable epilepsy

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):	01-04-2019
Enrollment:	72
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
NA

Ethics review

Positive opinion

Date:	05-11-2019
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	NL8138
Other	METC erasmus : MEC-2019-0127

Study results

Summary results
NA