A multicentre prospective observational cohort study of incidence, acute care and recovery in the first year after moderate/severe traumatic brain injury in adults in the Netherlands.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Injuries NEC
Study type	Observational non invasive

Summary

ID

NL-OMON30993

Source
ToetsingOnline

Brief title
POCON

Condition

- Injuries NEC
- Neurological disorders NEC

Synonym
Head injury, Traumatic Braininjury

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Neurotrauma, Observational, Prospective, Traumatic Brain Injury

Outcome measures

Primary outcome

Primary: GOSe

Secondary outcome

Secondary:

a. General questions (eg. work, history)

b.SF36

c. Pain score list

d. VVV (Fatigue questionnaire)

e. RPQ (Rivermead)

f. SVL (post-traumatic stress)

g. BDI (depression)

h. GOSE

i PQOL (Quality of life)

j. ESS (sleep scale)

k. SCL-90 (Complaints list)

l. VOW (Well being)

Assessment of economic costs will be according to the *letsel last model*

developed by Consument en Veiligheid

Study description

Background summary

The incidence of TBI is high, in the international literature varying between 100 and 300 per 100,000, with the highest incidence occurring in men, aged 15 to 24 years. The average age of patients with TBI is 30 years (1). Only one study estimated the incidence of TBI, in the catchment area of the Academic Hospital Maastricht, in the Netherlands. The incidence rate of traumatic head or brain injury in 1997 was 836/100,000 and the incidence of admission 88/100,000 (1).
Recent data however indicate an increase in average age and a larger contribution of elderly patients with TBI. Of all head injuries approximately 10% will be diagnosed with severe traumatic brain damage. Severe TBI is a life threatening disease of predominantly young persons with a 30% case fatality rate. Severe disabilities persist in over 50% of survivors. The young age at which severe TBI occurs and the 50% overall poor outcome explain why the loss of productive years is greater than that of subarachnoid haemorrhage and comparable to ischemic stroke.

Study objective

The main objective of this multicentre interdisciplinary study is to systematically aggregate data on moderate and severe traumatic brain injury patients in a national database. This database will serve to:
a. get an estimation of the incidence of moderate/severe traumatic brain injury
b. investigate variability in acute care management and identify areas for improvement of acute care
c. assess variability in resource allocation for post acute care and investigate determining factors.
d. quantify residual disability in survivors and provide an estimate of cost burden
e. better target prevention campaigns

Secondary goals:

- to stimulate national network collaboration between researchers
- to increase awareness of the problem in the community
- to enable future extension of activities in the direction of translational research in the Netherlands.

- initiate a network collaboration to permit long term longitudinal studies on prevalence and impact of TBI related disability in the Netherlands.

Study design

Methods: Multicentre observational cohort study
Study population: Patients (age >= 16) with moderate to severe traumatic brain injury.
Number of patients: Estimated 500.
Duration of the study: 2 years.
Inclusion criteria: Moderate and severe TBI. Moderate TBI is defined as a hospital admission GCS 9- 12 (m/f). Severe TBI is defined as a hospital admission GCS =< 8 (m/f). Admitted within 72 hours postinjury to one of the participating centres.
Treating physicians (neurospecialist, traumatologist, intensive care physician) involved in resuscitation of the patients at the emergency department will be asked to fill out a short questionnaire at the time the patient leaves the emergency department if they estimate that the patient will be dead or alive after 6 months and if alive will be in a vegetative state, severly disabled (GOSe 3-4) moderately disabled (GOSe 5-6) or recovered (GOSe 7-8)
For the purpose of this study the following data will be recorded in each centre: age, sex, medical history, pre-injury working status, referral status, GCS, pupillary reactions, overall injury severity (measured with the Injury Severity Score (ISS)(4), the Trauma Coma Databank (TCDB) CT score (all initial CT-scans will be send to the coordinating centre and read by one rater)(5), intracranial and systemic operations, the occurrence of hypoxia (defined as a PaO2 < 8kPa or a SaO2 < 90%) and hypotension (defined as a systolic blood pressure < 90 mm Hg), duration of coma and post traumatic amnesia. During the ICU registration of the occurrence of secondary complications: hypoxia, hypotension and treatment approaches employed. Total hospitalization time (on wards and ICU) will be registered.
At discharge: allocation of post acute care resource i.e home, rehabilitation centre, nursing home.

Follow up: at 6 months and 12 months
Six and 12 months post injury a Glasgow Outcome Score-extended as well as an employment and rehabilitation status will be obtained by personal or telephone interview.
At these time points also postal questionnaires including an informed consent letter will be send to all consecutive patients of the four centres who left the hospital alive. Using pre-stamped return envelopes all questionaires can be returned to the coordinating centre.
If no response can be obtained the general practitioner will be approached or a specialist known to be involved in treating the patient to obtain the information. If the patient has moved, the municipality register of the last known residence will be contacted to trace the patient.

In addition to general questions about the patient*s demographics, education and rehabilitation status, the questionnaire booklet contains the following self-report scales:

a. General questions (eg. work, history)
b.SF36
c. Pain score list
d. VVV (Fatigue questionnaire)
e. RPQ (Rivermead)
f. SVL (post-traumatic stress)
g. BDI (depression)
h. GOSE
i PQOL (Quality of life)
j. ESS (sleep scale)
k. SCL-90 (Complaints list)
l. VOW (Well being)

Study burden and risks

In the period of half a year, the patient has to complete a postal questionnaire. It will take 45 minutes to complete the questionnaire.

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

Moderate and severe Traumatic Brain Injury (TBI). Moderate TBI is defined as a hospital admission Glasgow Coma Scale (GCS) 9- 12 (m/f). Severe TBI is defined as a hospital admission GCS <= 8 (m/f).
Admitted within 72 hours postinjury to one of the participating centres and aged 16 years or older.

Exclusion criteria

Aged below 16 years
Mild TBI (GCS > 12)

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2007
Enrollment:	500
Type:	Anticipated

Ethics review

Approved WMO
Application type: First submission

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL19670.091.07