Impact of early intervention in the Emergency Department on post concussion symptoms in patients with mild traumatic brain injury (MTBI).

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The goal of this trial is to evaluate the effect of standardized oral, written and audiovisual information, given in the emergency department, on the development and severity of post traumatic symptoms in patients with mild traumatic brain injury...

Ethical review	Not approved
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON38704

Source
ToetsingOnline

Brief title
Impact of early intervention on post concussion symptoms in MTBI.

Condition

- Other condition

Synonym
concussion, Mild head trauma

Health condition

Posttraumatische klachten na LTH

Research involving

Human

Sponsors and support

Primary sponsor: HagaZiekenhuis
Source(s) of monetary or material Support: HAGA Ziekenhuis

Intervention

Keyword: Early intervention, Emergency Department, Mild traumatic head injury, Post concussion symptoms

Outcome measures

Primary outcome

Presence of post traumatic symptoms, as measured with th Riversmead Post

Concussion Questionnaire, 1 week and 3 months after MTBI.

Secondary outcome

Return to work or other normal daily activities

Study description

Background summary

The Dutch Institute for Healthcare Improvement (CBO) guidelines, suggest that providing MTBI patients with standardized written information in the early phase in the emergency department, may positively influence the presence and severity of post traumatic symptoms. However, there is a pausity of evidence supporting this suggestion.

Study objective

The goal of this trial is to evaluate the effect of standardized oral, written and audiovisual information, given in the emergency department, on the development and severity of post traumatic symptoms in patients with mild traumatic brain injury after 1 week and 3 months.

Study design

Double-blind randomized controlled trial

Intervention

Patients will be informed and requested for their informed consent. If included, patients will be assigned to either an intervention or a control group. Both groups will be provided with standardized basic information about their treatment and follow-up. The intervention group will receive additional extensive written and audiovisual information, containing background information on MTBI and suggestions on possible coping strategies for post traumatic complaints.

Study burden and risks

Included patients will have a longer stay of about 10-15 minutes on the emergency department, due to logistical factors and the fact that they will receive extra information from their treating physician. Further, patients agree to be contacted by phone twice, for an interview of an estimated 20 minutes. There are no direct healthrisks associated with the participation of this study. Patients receiving the additional information in the intervention group, could possibly benefit from the positive effect on their post-traumatic symptoms.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Aldult patients with mild traumatic brain injury (MTBI) admitted to the emergency department (ED)

Exclusion criteria

Not able to speak or write Dutch
Suffering from mental retardation or dementia
Abnormal head CT
Neurological impairment

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	714
Type:	Anticipated

Ethics review

Not approved

Date:	23-12-2013
Application type:	First submission
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	NL43651.098.13