Mild traumatic brain injury and Outcomes with VIsual patient Education (MOVIE), a randomised controlled trial.

Gepubliceerd: 25-10-2015 Laatst bijgewerkt: 18-08-2022

Our hypothesis is that receiving written and audio-visual patient information will reduce the frequency and severity of post-concussion symptoms in patients with MTBI.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26501

Bron
NTR

Verkorte titel
MOVIE-trial

Aandoening

Mild Traumatic Brain Injury (MTBI)
Licht traumatische Hoofd-/Hersenletsel (LTH)

Ondersteuning

Primaire sponsor: Erasmus Medical Center
Medical Centre Haaglanden
Sint Franciscus Vlietland Groep
Westfriesgasthuis
Overige ondersteuning: De Nederlandse Hersenstichting

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The occurence and severity of post-concussion symptoms measured by the ‘Rivermead Post-Concussion Questionnaire’ at 1 week and 3 months

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Mild traumatic brain injury (MTBI) is a common diagnosis at the Emergency department (ED). It is estimated that approximately 85,000 patients in the Netherlands suffer from MTBI each year, of whom 12,580 patients are seen at the ED of Dutch hospitals. In the first weeks to months after MTBI 17-78% of patients suffer from post-concussion symptoms. Previous studies indicate that knowledge and understanding of post-concussion symptoms by the patient may reduce incidence and/or severity of such complaints.

Objective: Our main objective is to study the effect of patient information on occurrence and severity of post-concussion symptoms in patients with MTBI.

Study design: A multi-centre prospective study will be conducted in two phases. Phase 1 is measurement of standard care. Phase 2 is a Randomized Controlled Trial (RCT), comparing standard management, with two intervention groups.

Study population: All patients >18 years with MTBI attending the ED may be eligible for inclusion.

Intervention (if applicable): Patients will receive a printed folder (written information) in the first intervention group, and in the second intervention group patients will receive written information and they will be asked to watch a video explaining the course of posttraumatic symptoms.

Main study parameters/endpoints: The primary outcome will be the occurrence and severity of post-concussion symptoms at one week and three months after attending the ED.

Doel van het onderzoek

Our hypothesis is that receiving written and audio-visual patient information will reduce the

frequency and severity of post-concussion symptoms in patients with MTBI.

Onderzoeksopzet

1 week and 3 months

Onderzoeksproduct en/of interventie

An online video with discharge instructions will be shown, and/or a link to the video will be provided in the leaflet.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients attending the ED of the participating centres with MTBI according to the definition of the Dutch institute for healthcare improvement (CBO):

- Every trauma to the head with a Glasgow Coma Scale score at first examination greater than 13,

- Post-traumatic loss of consciousness less than 30 minutes,

- and Post-traumatic amnesia not more than 24 hours

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Intracranial abnormality on CT-scan

- Focal Neurological deficit

- Language barrier

- No informed consent

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-12-2015
Aantal proefpersonen:	1152
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	25-10-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5355
NTR-old	NTR5465
Ander register	Medische Ethische Commissie : MEC-2015-546

Resultaten