Complement Inhibition: Attacking the Overshooting Inflammation @fter Traumatic Brain Injury

Gepubliceerd: 17-02-2020 Laatst bijgewerkt: 19-03-2025

The hypothesis is that random assignment to C1-INH in patients with moderate and severe TBI will experience a reduction in ICP directed therapy intensity levels (TIL) compared to random assignment to placebo (difference of 2.2). Secondary, if...

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

Samenvatting

ID

NL-OMON29423

Bron
NTR

Verkorte titel
CIAO@TBI

Aandoening

Traumatic Brain Injury

Ondersteuning

Primaire sponsor: Leiden University Medical Center
Overige ondersteuning: Dutch Brain Foundation and Takeda Pharmaceutical Company

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Efficacy: Therapy Intensity Level (TIL) scale and GOS-E at 6 months
Safety: Complication rate

Toelichting onderzoek

Achtergrond van het onderzoek

Severe Traumatic Brain Injury (s-TBI) is a major cause of death and disability across all ages. Besides the primary impact, the pathophysiologic process of major secondary brain damage consists of a neuroinflammation response that critically leads to irreversible brain damage in the first days after the trauma. A key catalyst in this inflammatory process is the complement system. Inhibiting the complement system is therefore considered to be a potentially important new treatment for TBI, as has been shown in animal studies. Therefore, this trial aims to study the safety and efficacy of C1-inhibitor Cinryze, an approved inhibitor of the complement system, compared to placebo in patients with s-TBI. By temporarily blocking the complement system we hypothesize limitation of secondary brain injury and more favourable clinical outcome for TBI patients due to a decrease in the posttraumatic neuroinflammatory response.

Doel van het onderzoek

The hypothesis is that random assignment to C1-INH in patients with moderate and severe TBI will experience a reduction in ICP directed therapy intensity levels (TIL) compared to random assignment to placebo (difference of 2.2). Secondary, if efficacy is proven on the TIL scale, a difference of the GOSE at six months will be evaluated. Furthermore, no difference should be detected in complication rate during hospitalization between the two groups.

Onderzoeksopzet

Hospital admission, hospital discharge, 3, 6 and 12 months follow-up

Onderzoeksproduct en/of interventie

(1) 6000 IU C1-INH intravenously
(2) Placebo 0.9% saline

Contactpersonen

Publiek

Leiden University Medical Center
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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age at admission ≥ 18 years and < 65 years;
- Clinical diagnosis of traumatic brain injury with GCS < 13 (with intracranial deviations);
- Catheter placement for monitoring and management of increased ICP for at least 24 hours.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- A clear, non-traumatic cause of low GCS (e.g. toxic, cardial) on admission;
- Not expected to survive more than 24 hours after admission;
- Brain death on arrival in the participating centres;
- Severe pre-trauma disability, defined as being dependent on other people;
- Known prior history of sensibility to blood products or Cinryze;
- Patients with a history of hereditary angioedema;
- Patients with a history of thrombosis;
- Pregnant women.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-11-2020
Aantal proefpersonen:	106
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
N/A

Ethische beoordeling

Positief advies

Datum:	17-02-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 52831
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8387
CCMO	NL72551.058.20
OMON	NL-OMON52831

Resultaten

Samenvatting resultaten
N/A