Cerebral Haemorrhage associated Inflammation: a PET/MRI Study

Gepubliceerd: 13-08-2020 Laatst bijgewerkt: 18-08-2022

We hypothesize that serum inflammatory markers, BBB integrity and PHO are associated with perihematomal inflammation.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON29665

Bron
NTR

Verkorte titel
CHIPS

Aandoening

Intracerebral hemorrhage

Ondersteuning

Primaire sponsor: Radboudumc
Overige ondersteuning: Dutch Heart Foundation

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary outcome is perihematomal oedema on MRI at day 7±1, which will be correlated with perihematomal uptake of 18F-DPA-714 on PET imaging at day 3±1 as a measure of neuroinflammation.

Toelichting onderzoek

Achtergrond van het onderzoek

Spontaneous intracerebral haemorrhage yearly affects over 6000 patients in the Netherlands. It is the deadliest stroke subtype, with a 30-day case-fatality of 40%. Of patients surviving, only few gain independence. However, effective treatment options are still lacking. This is reflected in het prognosis which has not improved over the last 30 years. Inflammation is known to play a vital role in the development of secondary brain injury related to intracranial haemorrhage. The release of blood products in the brain parenchyma leads to an activation of the immune system. This subsequently leads to destruction of the blood brain barrier and the formation of perihematomal oedema. In vivo studies linking serum inflammatory markers, blood brain barrier disruption and perihematomal oedema with perihematomal inflammation are lacking.
The CHIPS study strives to assess this relation in patients with acute, spontaneous intracerebral haemorrhage through blood sampling and MRI and PET-CT imaging. This will provide essential insights for the development of new treatment procedures to ameliorate secondary brain injury in intracranial haemorrhage.

This study has a prospective, observational cohort study design.

Doel van het onderzoek

We hypothesize that serum inflammatory markers, BBB integrity and PHO are associated with perihematomal inflammation.

Onderzoeksopzet

Patients will undergo blood sample collection at day 0, 1, 3 and 7.
At day 3±1, patients will undergo a 18f-dpa-714 PET-CT scan.
At day 7±1, patients will undergo a (DCE)-MRI-scan

Onderzoeksproduct en/of interventie

Not applicable

Contactpersonen

Publiek

Radboudumc Nijmegen
Maaike Cliteur

0650155723

Wetenschappelijk

Radboudumc Nijmegen
Maaike Cliteur

0650155723

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age ≥ 18 years;
2. Supratentorial non-traumatic ICH confirmed by CT, without a confirmed causative lesion on admission CT-angiography or other known underlying lesion;
3. Minimal haemorrhage volume of 10mL;
4. Inclusion within 24 hours after symptom onset;
5. Patient’s or legal representative’s informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Severe infection at admission, requiring antibiotic treatment;
2. Use of immunosuppressive or immune-modulating therapy at admission (see appendix A);
3. Pre-stroke modified Rankin Scale score ≥ 3
4. Severe ICH, unlikely to survive the first 72 hours (defined as Glasgow Coma Scale score < 6 at time of consent);
5. Pregnancy or breast-feeding;
6. Standard contraindications to MRI;
7. Administration of a radionuclide within 10 physical half-lives prior to study enrolment.
8. Known prior allergic reaction to gadolinium contrast or one of the constituents of its solution for administration;
9. Severe renal impairment (eGFR <30ml/min/1.73m);
10. Planned neurosurgical haematoma evacuation.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2020
Aantal proefpersonen:	10
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
Not applicable

Ethische beoordeling

Positief advies

Datum:	13-08-2020
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	NL8831
Ander register	Radboudumc : 109882

Resultaten