Cerebral Haemorrhage associated Inflammation: a PET/MRI Study

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON29665

Source
NTR

Brief title
CHIPS

Health condition

Intracerebral hemorrhage

Sponsors and support

Primary sponsor: Radboudumc
Source(s) of monetary or material Support: Dutch Heart Foundation

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Secondary study parameters are the association between and the perihematomal uptake of 18F-DPA-714 on PET imaging at day 3±1 and blood barrier leakage Ktrans as measured with DCE-MRI on day 7±1. Furthermore the correlation with serum inflammation markers (comparing day 1, 3 and 7 to baseline) will be assessed.

Study description

Background summary

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.

Study objective

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

Study design

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

Intervention

Not applicable

Contacts

Public
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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2020
Enrollment:	10
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
Not applicable

Ethics review

Positive opinion

Date:	13-08-2020
Application type:	First submission

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
NTR-new	NL8831
Other	Radboudumc : 109882

Study results