# MRI brain imaging in spontaneous intracerebral haemorrhage; pinpointing the underlying vascular disease

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Central nervous system vascular disorders |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON44852

**Source**
ToetsingOnline

**Brief title**
FETCH: Finding the ETiology in spontaneous Cerebral Haemorrhage

### Condition

- Central nervous system vascular disorders

**Synonym**
spontaneous intracerebral haemorrhage / brain bleeding

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Utrecht
**Source(s) of monetary or material Support:** ZonMw (Aspasia),Hartstichting (Clinical Established Investigator)

## Intervention

**Keyword:** Brain / cerebral / intracerebral hemorrhage / bleed, Etiology, Vascular

## Outcome measures

### Primary outcome

Number and distribution of markers for brain and vascular abnormalities and on

Magnetic Resonance Imaging (MRI).

Number and characteristics of CTA spot sign and haematoma growth.

### Secondary outcome

Not applicable

# Study description

### Background summary

Intracerebral haemorrhage (ICH) is the deadliest subtype of stroke. ICH not caused by trauma, vascular malformations, tumor or coagulopathy is lumped together as *primary* or spontaneous ICH. This umbrella term suggests that affected patients have the same disease, do not require further investigations to search for the underlying vascular disease and should be treated similarly. This simplification has slowed down progress in the field of ICH. Many questions regarding the underlying mechanism in ICH remain wide open. An initial step to unravel ICH etiology has been to try to attribute deeply located (non-lobar) ICH to hypertension and lobar ICH in elderly patients to cerebral amyloid angiopathy (CAA). This dichotomy is still an overtly insufficient simplification as many patients with non-lobar ICH do not have hypertension and cerebral amyloid angiopathy is found in at most one-third of patients with lobar haemorrhage. Recent studies indicate that the mechanisms involved in the deleterious effect of ICH may not be the same in all patients. Effective treatments for ICH can only be developed when we can better characterize the underlying vessel disease in patients with ICH and know the different mechanisms in the sequence of pathologic events triggered by the haemorrhage. The knowledge gained with this project will lead to new insights that will allow development of new and specific treatment targets for patients with ICH.

### Study objective

The overall aims of the proposed project are
1) to establish biomarkers for identification of the underlying vascular disease in patients with ICH and
2) to characterize whether disruption of the blood-brain barrier, a key factor in secondary brain injury after ICH, varies according to the underlying cause.
3) to determine whether timing invariant CT angiography (TI-CTA) can identify patients at risk of haematoma expansion (HE) and poor outcome more accurately than conventional CTA
With this knowledge we will be able to develop new targeted treatments and design targeted randomized clinical trials for patients with ICH.

**Study design**

The study proposed here is a prospective multicenter cohort study.

**Study burden and risks**

The extent of burden and risks for this study are minimal. Gadolinium enhanced 3T MRI is performed in patients with ICH in routine clinical practice as part of the workup to find an underlying cause of the ICH such as a tumor or an arteriovenous malformation, fistula, or a cavernous malformation, according to the guidelines by the American Heart Association 2010 and the European Stroke Organisation 2006. For substudy C, patients will recieve a low dose of extra radiation.. There is a very small maximum increased risk 0,006% a patient develops cancer as result of this study. This follow up scan is performed in routine clinical care in a subset of patients.

For the study all patients will undergo a 3T MRI, with a duration of approximately 30 minutes.Scanning with 7 Tesla (7T) MRI is not yet routine, but strict application of contra-indications minimizes the risk of complications. A 7T gadolinium enhanced MRI will take approximately 45 minutes.

A person who is close to the patient (partner, family member or friend) will be asked to complete the Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE), which will take approximately 15 minutes. The patient or a person close to the patients will be asked to fill in a questionaire regarding possible triggers of intracerebral hemorrhage, which will take 30-45 minutes.

Clinical follow up will be done at 3 months and 12 months by visits to the outpatient clinic or through standardized telephone interviews, including the TICS-M cognitive assessment. With this follow up information we will be able to study whether presence and severity of the MR markers are associated with poor outcome (modified Rankin score >3) at 3, 12, 24 and 48 months. Total time involved in participating in this study is between 105 and 210 minutes.

# 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

For substudy A - 3T unenhanced MRI scanning:
- Age >= 18 years
- ICH confirmed by CT
- 3T MRI scanning possible preferably within 10 days, but at least within 3 months of ICH diagnosis
- No obvious cause of ICH (tumor, vascular anomaly or trauma as cause of haemorrhage);For substudy B - 7T gadolinium enhanced MRI scanning:
- Participants of substudy A
- 7T MRI scanning possible preferably within 10 days, but at least within 3 months of ICH diagnosis;For substudy C - CT spot sign study:
- Age >= 18 years
- ICH confirmed by CT

- CTP and CTA has been performed on admission
- Non contrast CT possible within 48 hours after symptom onset.
- No obvious cause of ICH (tumor, vascular anomaly or trauma as cause of haemorrhage)

### Exclusion criteria

For substudy A - 3T unenhanced MRI scanning:
- Contraindications for MR imaging (see appendix A research protocol) ;For substudy B - 7T gadolinium enhanced MRI scanning:
- Impossibility to undergo MRI (claustrophobia, implants or metal objects in or around the body).
- Known prior allergic reaction to gadolinium contrast or one of the constituents of its solution for administration.
- Severely impaired renal function (severe renal insufficiency, GFR <30 ml/min/1.73 m; or nephrogenic systemic fibrosis / nephrogenic fibrosing nefropathy (NSF/NDS))
- Pregnancy;For substudy C - CT spot sign study:
- Pregnancy ;For all studies:
- No informed consent obtained from patient or legal representative

## Study design

### Design

**Study type:** Observational invasive

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| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Basic science |

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 18-10-2013 |
| Enrollment: | 300 |
| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 12-08-2013 |
| Application type: | First submission |
| Review commission: | METC NedMec |
| Approved WMO Date: | 24-03-2014 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 16-07-2015 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 22-03-2017 |
| Application type: | Amendment |
| Review commission: | METC NedMec |

# 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 | NL43286.041.13 |

# Study results

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| Date completed: | 31-12-2022 |

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| Actual enrolment: | 221 |