# DEBBIE-ASL Pilot

Published: 13-01-2023
Last updated: 21-09-2024

Implement BBB-ASL at VUmc and assess the reliability and reproducibility of f measurements in healthy volunteers and patients with glioma

| | |
|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Nervous system neoplasms malignant and unspecified NEC |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON51668

**Source**
ToetsingOnline

**Brief title**
DEBBIE-ASL Pilot

### Condition

- Nervous system neoplasms malignant and unspecified NEC

**Synonym**
brain tumor, glioma

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Amsterdam UMC
**Source(s) of monetary or material Support:** Ministerie van OC&W

### Intervention

**Keyword:** Arterial spin labeling, blood-brain barrier, glioma, MRI

## Outcome measures

### Primary outcome

pilot study

- absolute values of perfusion and permeability parameters with standard

deviation

- intraclass coefficient and Bland-Altman for repeatability

### Secondary outcome

- classification possible according to tissue type (healthy, tumour, type of

tumour)

# Study description

### Background summary

BBB-ASL, or DEBBIE-ASL, is a new arterial spin labeling magnetic resonance imaging (MRI) technique to measure perfusion in the human brain as well as quantify the leakage of the blood-brain barrier, the permeability. It does not require contrast agent like gadolinium and is fully non-invasive. The blood-brain barrier (BBB) is usually tight (no permeability), but typically becomes permeable when the blood vessel walls are attacked by inflammation or tumor. In brain tumors, perfusion is often also altered due to build-up of tumor blood vessels. Having an MRI tool which can visualize and measure both permeability and perfusion in the brain noninvasively, can be of great value for brain tumor diagnostics, glioma in particular. Currently, VUmc Radiology Department aims to start a study with the BBB-ASL technique in dementia (registration: NL.029.22), but we need a pilot study to establish the technique also for neuro-oncological patients.

### Study objective

Implement BBB-ASL at VUmc and assess the reliability and reproducibility of f measurements in healthy volunteers and patients with glioma

### Study design

Observational, prospective pilot MRI imaging study

**Study burden and risks**

Er is geen interventie. Alle deelnemers zullen een extra MRI scan couplet van 10 minuten krijgen tijdens een klinische MRI (patiënten) of drie coupletten van deze scans achter elkaar (vrijwilligers, 20+10 minuten in totaal). Bij patiënten zal de BBB-ASL MRI-sequentie tweemaal worden gescand vlak voor toediening van gadoliniumcontrast (dat zelf deel uitmaakt van het standaardprotocol). Bij gezonde vrijwilligers wordt de BBB-ASL MRI twee keer gescand samen met een standaard T1-gewogen MRI-scan van de hersenen, daarna verlaten zij de scanner voor één minuut, gaan dan weer naar binnen, de BBB-ASL scan wordt weer twee keer uitgevoerd, dan gaan zij een dag weg en komen na één tot twee weken terug voor nog twee BBB-ASL MRI-scans (in totaal 6 scans van elk 5 minuten).

De gezonde vrijwilligers moeten twee keer naar VUmc komen voor de scans. De patiënten krijgen de BBB-ASL tijdens een reguliere klinische scan. Voor de vrijwilligers is dit in totaal 30 minuten in de MRI-scanner, voor de patiënten is dit nog eens 10 minuten bovenop hun reguliere MRI-scan van 25 minuten van de tumor.

Er is geen risico dat groter is dan het risico voor gewone MRI. De vrijwilligers zijn meestal al eerder in de MRI geweest, en de meeste patiënten zullen dat ook zijn.

# Contacts

**Public**
Amsterdam UMC

De Boelelaan 1117
Amsterdam 1081HV
NL
**Scientific**
Amsterdam UMC

De Boelelaan 1117
Amsterdam 1081HV
NL

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

• age minimally 18 and legally able to give informed consent
• both sexes allowed

For patients:
• patient of Amsterdam University Medical Centre, location VUmc, with high suspicion of de novo brain tumor or recurrent brain tumor patient receives clinically indicated MRI
• no other concurrent brain pathology at the time of diagnosis

For healthy volunteers:
• no history of significant brain pathology

## Exclusion criteria

• Not fitting the inclusion criteria
• Contraindication for MRI
• Dependent relationship to PI (family, PhD student, etc.)
Pregnant or breast-feeding

# Study design

## Design

**Study type:** Observational non invasive

| | |
|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Diagnostic |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 04-05-2023 |
| Enrollment: | 30 |
| Type: | Actual |

### Medical products/devices used

| | |
|---|---|
| Generic name: | MRI sequence arterial spin labeling |
| Registration: | No |

## Ethics review

Approved WMO

| | |
|---|---|
| Date: | 13-01-2023 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |

## 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 | NL81819.029.22 |