Quantitative MRI for Blood Brain Barrier integrity Assessment without Gadolinium Based Contrast Agents

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To compare the clinical value of MR quantitative parametric maps versus the use of GBCA MRI.

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON56940

Source
ToetsingOnline

Brief title
MRI BBB Integrity assessment GBCA-Free

Condition

- Other condition

Synonym
parametric mapping in predicting the post-contrast enhancement in brain matter

Health condition

Hersenscan gebruikmakend van contrast

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Brain scan, gadolinium based contrast agents (CBCA), quantitative multi-parametric MR pulse sequence.

Outcome measures

Primary outcome

Prediction of BBB breakdown

Secondary outcome

Evaluation of percentage of PD, T1 and T2 change related to the GBCA dose and

patient*s weight.

Study description

Background summary

The Magnetic Resonance (MR) Physics research group has identified a potential biomarker based on non-invasive quantitative MRI technique that could assess the blood brain barrier integrity without the necessity of toxic gadolinium based contrast agents (GBCAs). A first endpoint is to verify the ability of quantitative parametric mapping in predicting the post-contrast enhancement, previous to the GBCA injection. A second endpoint is to evaluate the effective quantitative percentage of change in the post-contrast T1 and T2 value due to the GBCA. The rational of GBCA is to shorten the natural long T1 and T2 values.

The evaluation of the percentage of change of T1 due to the GBCA could facilitate a new model where the administered GBCA dose could be reduced to that amount that produces a minimum detectable percentage of change with MRI.

To evaluate the clinical value of this new approach, this new biomarker for BBB integrity has to be compared to the conventional use of GBCA in large cohort of patients who undergone MRI with contrast agent because the current clinical state of the art.

Study objective

To compare the clinical value of MR quantitative parametric maps versus the use of GBCA MRI.

Study design

Observational diagnostic study.

Study burden and risks

Burden: 5 extra minutes MRI examination . No risk associated, Potential benefit for those patients with recurrent MRI exams with contrast agent who could potentially not need dose of GBCA in future visits or , at least, a smaller amount of GBCA based on the quantitative detection of the percentage of change

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

Age => 18 year
Patients from these pathologies will be included:
* Brain Tumors.
Rationale: Contrast MRI is instrumental in detecting brain tumors, as these agents help to delineate tumor margins, show the vascular supply, and highlight areas of neovascularity or breakdown of the normal blood-brain barrier.
* Infections.
Rationale: In cases of brain infections like abscesses, encephalitis, or meningitis, contrast MRI can help in defining the extent of the infection and differentiating it from other pathologies.
* Multiple Sclerosis (MS).
Rationale: For MS, contrast MRI can help in identifying active versus inactive lesions. Active lesions will typically take up the contrast agent due to the breakdown of the blood-brain barrier.
* Inflammatory Conditions.
Rationale: Diseases like sarcoidosis or autoimmune disorders such as vasculitis may also be evaluated with contrast MRI to understand the extent of inflammation and its effects on brain tissue.
* Demyelinating Diseases.
Rationale: Besides MS, other demyelinating conditions might also show contrast enhancement where there is active inflammation.
* Metastasis.
Rationale: Contrast MRI helps in the detection of metastatic cancer to the brain, often revealing multiple lesions with a characteristic appearance.
* Post-Treatment Evaluation.
Rationale: Following surgery, radiation, or chemotherapy, contrast MRI can help in monitoring for recurrence or progression of disease.

Exclusion criteria

Patients with other pathologies even those which contrast agent is usually prescribed such as vascular malformations, aneurysms, congenital malformations and other vascular anomalies are excluded.
A patient who meets any of the following criteria will be excluded from participation in this study:
* Subjects with a typical contra-indication to an MRI exam.
* Subjects with metal implants.
* Subjects who have a documented allergy to MRI contrast media or a

contra-indication for contrast-media or will not undergo contrast-enhanced MRI.
* Woman who are pregnant or lactating
* Having any physical or mental status that interferes with the informed consent procedure

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2024
Enrollment:	230
Type:	Anticipated

Medical products/devices used

Generic name:	kwantitative multiparametric mapping
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	09-08-2024
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL86761.078.24