7T metabolic MRI in glioma & epilepsy

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To characterize glioma and epileptogenic tissue with 7T metabolic MRI, and validate their metabolic imaging characteristics with histopathological measures.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Nervous system neoplasms malignant and unspecified NEC
Study type	Observational invasive

Summary

ID

NL-OMON55209

Source
ToetsingOnline

Brief title
GliMEpi

Condition

- Nervous system neoplasms malignant and unspecified NEC
- Seizures (incl subtypes)

Synonym
brain cancer; epilepsy:convulsion disorder, glioma: brain tumor, seizure disorder

Research involving
Human

Sponsors and support

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

Intervention

Keyword: epilepsy, glioma, histopathology, metabolic MRI

Outcome measures

Primary outcome

Metabolic imaging measures of different molecules of interest in glioma tissue (including but not limited to: N-acetylaspartate (NAA), choline, creatine, 2HG and cystathionine) and epileptogenic tissue (including but not limited to glutamate, gamma-aminobutyric acid (GABA) and iron) as acquired with 7T metabolic MRI.

Secondary outcome

Comparison of the metabolic imaging measures of different molecules of interest with histopathological measures.

Study description

Background summary

Conventional MRI has been established as one of the main pillars of neuroimaging. However, for several neurological diseases, it can be relatively limited in detecting or delineating pathological tissue (e.g. MRI negative epilepsy and disease spread in glioma), and it is usually not specific enough to provide a definitive diagnosis with the same certainty as histopathological analysis (e.g. tumor progression versus radiation necrosis and relevant molecular subtypes of low grade glioma). Metabolic MRI - visualizing the metabolic *phenotype* of diseases - can improve diagnostic specificity whereas ultrahigh magnetic field strengths (7T) can improve diagnostic sensitivity as well as boost the diagnostic specificity of metabolic MRI. The goal of this study is therefore to acquire multiple metabolic imaging characteristics with 7T (metabolic) MRI of two common neurological diseases that are diagnostically limited by conventional MRI and receive surgical treatment (glioma and epilepsy), thus allowing for validation of the metabolic phenotype with the true molecular phenotype defined by histopathology to eventually use the acquired metabolic imaging characteristics in the clinical diagnostic process.

Study objective

To characterize glioma and epileptogenic tissue with 7T metabolic MRI, and validate their metabolic imaging characteristics with histopathological measures.

Study design

An observational non-therapeutic cohort study with two cohorts.

Study burden and risks

MRI is an invasive imaging modality, involving high magnetic fields, which to the best of our knowledge is not associated with short or long-term adverse effects. Potential burdens are loud acoustic scanner noise and slight discomfort (dizziness) that may occur due to peripheral nerve stimulation. Subjects with glioma-associated epilepsy will receive intravenous contrast administration, which is a minimal invasive procedure with minor risks not different to when applied in clinical practice. Application of the infusion may be painful. Participating patients will not benefit from the results of this study. However, future patients may benefit as this study could lead to better understanding of glioma and epilepsy physiology, improving diagnosis and treatment evaluation with consequent treatment decisions. Furthermore, it may lead to the discovery of new (molecule-based) treatment options.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Aged 16 years or over and able to exercise their free will (capacitated);
• Diagnosed with glioma-associated epilepsy or focal epilepsy with a relevant lesion on conventional MRI or PET;
• Scheduled for surgical treatment;
• Informed and having given informed consent

Exclusion criteria

• The presence of claustrophobia;
• MRI-specific exclusion criteria, such as metallic implants and pregnancy;
• Refusal or inability to provide informed consent.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-06-2021

Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	Philips Achieva 7.0T
Registration:	No

Ethics review

Approved WMO Date:	08-12-2020
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	31-12-2021
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	NL74932.041.20