Neuroinflammation in frontotemporal lobar degeneration: a multimodal biomarker study

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The aim of this study is two-fold:1.To elucidate the role of neuroinflammation in FTLD2.To identify biomarkers to predict and monitor disease progression in FTLD3.To differentiate FTLD-TDP from FTLD-tau during life using biomarkers for...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Movement disorders (incl parkinsonism)
Study type	Observational invasive

Summary

ID

NL-OMON54174

Source
ToetsingOnline

Brief title
Neuroinflammation in FTLD

Condition

- Movement disorders (incl parkinsonism)
- Dementia and amnestic conditions

Synonym
dementia and parkinsonism

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: externe subsidies Alzheimer Nederland;JPND

en NIH

Intervention

Keyword: biomarkers, dementia, MRI, parkinsonism

Outcome measures

Primary outcome

Differences between patients with FTLD-TDP, patients with FTLD-tau in the symptomatic and presymptomatic stage and healthy controls in CSF and MRI measures for neuroinflammation and correlation with clinical measures at baseline and follow-up.

Secondary outcome

na

Study description

Background summary

Frontotemporal lobar degeneration (FTLD) presents with variable degrees of behavioral disturbances, language and executive dysfunction and parkinsonism, with major impact on daily live functioning, for which no cure is available. Insight in the pathophysiology is crucial for treatment development. Recent research convincingly shows that neuroinflammation occurs in FTLD, however its role in the disease process is unknown. We will use a multimodal biomarker approach, including high-field 7T MRI and fluid biomarkers, to elucidate the role of neuroinflammation in the disease and thereby determine the potential of anti-inflammatory drugs to alter the disease course and to identify appropriate biomarkers for upcoming clinical trials.

Study objective

The aim of this study is two-fold:
1.To elucidate the role of neuroinflammation in FTLD
2.To identify biomarkers to predict and monitor disease progression in FTLD
3.To differentiate FTLD-TDP from FTLD-tau during life using biomarkers for

neuroinflammation

Study design

Longitudinal observational study

Study burden and risks

The study includes a baseline visit in the Erasmus Medical Center and in the Leiden University Medical Center and a follow-up visit in the Erasmus Medical Center after one year. In the Leiden University Medical Center participants will undergo a 7T MRI scan, which has no known health consequences. Contraindications for MRI will be carefully checked. In the Erasmus Medical Center, participants will undergo physical and neuropsychological evaluation, and a vena puncture at baseline and follow-up and a lumbar puncture only at baseline. Physical and neuropsychological evaluation have no known health risks. The risk of lumbar punctures is almost negligible, as long a contraindications are carefully checked. With the use of a thin, non-traumatic, needle the risk of a headache, which is the most common complication, is less than 10%. Other complications such as meningitis and subdural spinal haematoma are extremely rare.

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

- Ability to undergo MRI scanning
- For probable FTLD-tau: a clinical diagnosis of PSP, CBS or nfvPPA, or any clinical FTLD spectrum diagnosis with a proven MAPT mutation
- For probable FTLD-TDP: a clinical diagnosis of svPPA or any clinical FTLD spectrum diagnosis with a proven GRN mutation or C9orf72 repeat expansion
- For presymptomatic mutation carriers: a MAPT mutation, GRN mutation or a C9orf72 mutation withouth clinical sign of a FTLD spectrum phenotype (CDR 0)
- For control subjects: no known neurological or psychiatric disorder

Exclusion criteria

- Other neurological or psychiatric disorder that may affect cognitive functions, such as a brain tumour, multiple sclerosis or drug or alcohol abuse or use of psycho-active medications
- CSF profile (β-amyloid, p-tau, t-tau) suggestive of AD pathology
- Clinical dementia Rating Scale (CDR) score >1
- Contra-indication to undergo MRI
- Contra-indication to undergo lumbar puncture

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-08-2023
Enrollment:	110
Type:	Actual

Medical products/devices used

Generic name:	Philips Achieva 7.0T MRI scanner
Registration:	No

Ethics review

Approved WMO

Date:	27-05-2022
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	25-04-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	13-12-2024
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL78272.058.21