Blood biomarkers in frontotemporal dementia: a longitudinal study

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To study the longitudinal dynamics of blood biomarkers, including NfL, in patients with frontotemporal dementia.

Ethical review	Approved WMO
Status	Pending
Health condition type	Structural brain disorders
Study type	Observational invasive

Summary

ID

NL-OMON44528

Source
ToetsingOnline

Brief title
Longitudinal blood biomarkers in frontotemporal dementia

Condition

- Structural brain disorders

Synonym
dementia, frontotemporal dementia, Pick's disease

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: biomarker, blood, frontotemporal dementia, longitudinal

Outcome measures

Primary outcome

1. Longitudinal dynamics of biomarkers in blood of patients with frontotemporal

dementia

2. Relationship between longitudinal change of blood biomarkers and severity

and rate of cognitive decline in patients with frontotemporal dementia.

Secondary outcome

NA.

Study description

Background summary

Of all patients with dementia, 5-10% suffer from frontotemporal dementia (FTD). It is the second most common cause of early onset dementia (<65 years). FTD is characterised by early behavioural and/or language impairment. Its clinical course is highly variable but inevitably leads to progressive cognitive decline. As of yet, there are no medical treatments to stop or slow down disease progression.

In recent years, the development of biomarkers for dementia has gathered much interest. Ideally, a biomarker in blood could contribute to early diagnosis and prediction of disease progression. Additionally, these blood biomarkers could be used to monitor effects of treatment in future medication trials. A very promising blood biomarker in FTD is neurofilament light chain (NfL). This protein is present in much larger quantities in FTD patients than in controls. Other such blood biomarkers are currently being researched.

As of yet, the study of blood biomarkers in FTD has been restricted to cross-sectional analyses. In order to apply biomarkers for medication trials in the future, it is essential to understand the longitudinal dynamics.
In this study, we aim to unravel the longitudinal dynamics of blood biomarkers, including NfL, in patients with FTD, by obtaining longitudinal blood samples and clinical information on disease progression.

Study objective

To study the longitudinal dynamics of blood biomarkers, including NfL, in patients with frontotemporal dementia.

Study design

Prospective observational study.

Study burden and risks

For this study, participants will be asked to visit the outpatient clinic of the Neurology department of the Erasmus MC annually for three consecutive years. During each visit, several validated questionnaires are filled out concerning cognitive functioning. A blood sample (total 34 ml) is collected through venipuncture. The risks of venipuncture are minimal; a possible risk is development of a hematoma at the puncture site.
The duration of each annual visit is roughly 45 minutes.
Whenever possible, visits will be planned in conjunction with regular outpatient appointments. If desired, patients and caregivers can opt for a study visit at the place of residence of the patient. These measures attempt to minimise the required effort from the patient and their caregiver.

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

Patients with frontotemporal dementia who visited our referral centre and were diagnosed according to International Consensus Criteria. All clinical subtypes will be included, both genetic and sporadic.

Exclusion criteria

Patients with a history of unrelated neurological disorders that could influence cognitive performance (such as normal pressure hydrocephalus, brain tumours, developmental disorders et cetera).

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2017
Enrollment:	80
Type:	Anticipated

Ethics review

Approved WMO Date:	27-11-2017
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	NL63268.078.17