Imaging in motor neuron diseases; biomarker research with MRI

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1) Identify and further explore the structural and functional brain alterations in ALS patients, PSMA patients annd PLS patients in comparison to healthy controls and ALS mimic sydromes, both cross-sectional and longitudinal; 2) Explore anatomical...

Ethical review	Not approved
Status	Will not start
Health condition type	Neuromuscular disorders
Study type	Observational invasive

Summary

ID

NL-OMON35176

Source
ToetsingOnline

Brief title
Imaging in MND

Condition

- Neuromuscular disorders

Synonym
motor neuron disease (MND), muscle disease

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Prinses Beatrix Fonds en ALS Stichting Nederland

Intervention

Keyword: imaging, motor neuron disease, MRI

Outcome measures

Primary outcome

1) Cortical thickness, measured in T1 weighted images. The imaging data will be compared with controls and ALS mimic syndromes and to non-affected cortical regions in the same subjects (3Tesla and/or 7Tesla); 2).Structural connectivity of motor pathways with DTI and deterministic fiber tracking. (3Tesla); 3) Brain functional connectivity with resting-state fMRI (3Tesla and/or 7Tesla); 4) Glutamate/GABA intensity with MR spectroscopy (7Tesla).

Secondary outcome

The structural changes will be regarded in relation to the clinical condition, duration of illness and clinical parameters of motor function.

Study description

Background summary

Neuropathological as well as radiological studies have demonstrated structural changes in brain and spinal cord of patients with ALS, for example white matter changes and cortical atrophy especially in the motor cortex.

Study objective

1) Identify and further explore the structural and functional brain alterations in ALS patients, PSMA patients annd PLS patients in comparison to healthy controls and ALS mimic sydromes, both cross-sectional and longitudinal; 2) Explore anatomical changes in asymptomatic family members of patients with familial ALS. 3) Investigate the correlations of anatomical changes with clinical variables.

Study design

Observational cross sectional and longitudinal study

Study burden and risks

The participants will undergo clinical assessment, 3Tesla and 7Tesla MRI in the UMC Utrecht. For the individual participant there are no direct benefits. The information acquired by this research project may provide new insights in diagnosing, measuring disease progression and pathogenesis of ALS/MND.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
3584 CX Utrecht
Nederland
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
3584 CX Utrecht
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

1. Patients: i) For ALS patients: definite, probable, probable-laboratory supported or possible ALS according to the revised El Escorial criteria (Brooks 2000); familial ALS is defined only if there is a family history of ALS. ii) For progressive spinal muscular atrophy (PSMA) or primary lateral sclerosis (PLS): patients with clinical diagnosis of PSMA or PLS, after excluding other diseases. iii) Patients with *ALS mimic syndromes*: patients suspected of mimic disorders (e.g. multifocal motor neuropathy, inclusion body myositis, cervical myeloradiculopathy, myasthenia gravis,
Kennedy*s disease). 2. Age 18 - 80 years (inclusive). 3. Capable of thoroughly understanding the study information given; has signed the informed consent.

Exclusion criteria

1) Tracheostomy, tracheostomal ventilation of any type, (non)-invasive ventilation; 2) Any history or presence of brain injury, epilepsy, psychiatric illness and other cerebral disease; 3) Any intoxication or medication known to have an association with motor neuron dysfunction, which might confound or obscure the diagnosis of motor neuron disease; 4) Presence of pronounced swallowing disorders (which make it dangerous to lie supine in the MRI scanner); 5) Contra-indication for 3 or 7Tesla MRI imaging (as established by the department); 6) Pregnancy

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	900

Type:	Anticipated

Ethics review

Not approved

Date:	17-11-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL38399.041.11