Imaging in motor neuron diseases; biomarker research with MRI

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1) To validate structural and functional changes (previous found in ALS patients) in other motor neuron disease and ALS mimicking syndromes and healthy control subjects 2) Explore brain alterations of asymptomatic family members in case of ALS, to...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Neuromuscular disorders
Study type	Observational invasive

Summary

ID

NL-OMON55454

Source
ToetsingOnline

Brief title
Imaging in MND

Condition

- Neuromuscular disorders

Synonym
ALS, 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: amyotrophic lateral sclerosis, motor neuron disease, MRI, neuroimaging

Outcome measures

Primary outcome

1) Cortical thickness, measured in T1 weighted images. The imaging data will be compared in patients (ALS, MND, ALS mimics) and controls (3Tesla);

2).Structural connectivity of motor pathways with DTI and deterministic fiber tracking (3Tesla); 3) Brain functional connectivity with resting-state fMRI (3Tesla).

Secondary outcome

The structural changes will be regarded in relation to genotype and clinical parameters (e.g. disease progression)

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) To validate structural and functional changes (previous found in ALS patients) in other motor neuron disease and ALS mimicking syndromes and healthy control subjects 2) Explore brain alterations of asymptomatic family members in case of ALS, to determine whether neuroimaging parameters show changes at an asymptomatic stage of the disease. 3) Investigate gene effects on neuropathology, associating genotypes with neuroimaging phenotypes. 4) Evaluate the added benefit of using MRI parameters in therapeutic research

Study design

Observational cross sectional and longitudinal study

Study burden and risks

The participants will undergo clinical assessment and 3Tesla MRI in the UMC Utrecht., with addidiontal follow-up in patients and controls will also undergo the same follow-up to study brain alterations longitudinally. 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. The risk associated with participation can be considered a minimal exceeding of negligible risk.

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)

Inclusion criteria

1a) 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 /with mimic disorders (e.g. multifocal motor neuropathy, inclusion body myositis, cervical myeloradiculopathy, myasthenia gravis, Kennedy*s disease, spinal muscular atrophy).
1b) Healthy controls without manifest diagnosis of motor neuron disease or ALS mimic
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 3Tesla MRI imaging (as established by the radiology 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:	Recruiting
Start date (anticipated):	03-07-2012
Enrollment:	2203
Type:	Actual

Ethics review

Approved WMO Date:	05-04-2012
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	06-08-2012
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	04-11-2014
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	30-11-2016
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	17-05-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	17-05-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	25-03-2021

Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	29-09-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	09-02-2023
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	NL38994.041.11