# Disease biomarkers in amyotrophic lateral sclerosis/motor neuron disease

Submission date Recruitment status [ ] Prospectively registered 11/08/2010 No longer recruiting [ ] Protocol [ ] Statistical analysis plan Registration date Overall study status 11/08/2010 Completed [X] Results [ ] Individual participant data **Last Edited** Condition category 12/09/2016 Nervous System Diseases

#### Plain English summary of protocol

Not provided at time of registration

# **Contact information**

#### Type(s)

Scientific

#### Contact name

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#### Contact details

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## Additional identifiers

Protocol serial number 6160

# Study information

#### Scientific Title

Disease biomarkers in amyotrophic lateral sclerosis/motor neuron disease

#### **Acronym**

#### **ALS Biomarkers Study**

#### **Study objectives**

This study will evaluate the expression of neurofilaments and of other relevant molecules in blood samples taken from individuals with amyotrophic lateral sclerosis at different time points during the development of the disease. Our aim is to validate easily accessible disease biomarkers functioning as reliable predictors of disease severity and capable of providing information about the stratification of the disease phenotypes. Control groups will include healthy individuals and patients with a compressive radiculopathy. Recruitment will take place in four motor neuron disease clinics serving a population of approximately 7,000,000 in North-East London, Herefordshire and Essex. A similar study is currently ongoing in animal models of the disease.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

MREC, ref: 09/H0703/27

#### Study design

Multicentre non-randomised interventional diagnosis trial

#### Primary study design

Interventional

#### Study type(s)

Diagnostic

#### Health condition(s) or problem(s) studied

Topic: Dementias and Neurodegenerative Diseases Research Network; Subtopic: Motor neurone disease; Disease: Motor neurone disease

#### Interventions

- 1. Blood tests
- 2. Venepuncture

Study entry: registration only

#### Intervention Type

Other

#### **Phase**

**Not Specified** 

#### Primary outcome(s)

The rate of neurological decline as measured by the ALS Functional Rating Scale Revised (ALSFR)

#### Key secondary outcome(s))

Not provided at time of registration

#### Completion date

01/02/2011

# **Eligibility**

#### Key inclusion criteria

- 1. Diagnosis of definite or probable amyotrophic lateral sclerosis (ALS) according to the El Escorial Criteria
- 2. Greater than 16 years of age, either sex

#### Participant type(s)

**Patient** 

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Sex

All

#### Key exclusion criteria

ALS/motor neuron disease (MND) patients unable to consent

#### Date of first enrolment

24/06/2009

#### Date of final enrolment

01/02/2011

#### Locations

#### Countries of recruitment

**United Kingdom** 

England

# Study participating centre Institute of Neurology

London United Kingdom WC1N 3BG

# Sponsor information

#### Organisation

Barts and The London NHS Trust (UK)

#### **ROR**

https://ror.org/00b31g692

# Funder(s)

#### Funder type

Charity

#### **Funder Name**

Motor Neurone Disease Association (UK) (ref: Mal.../Apr08/RF/6039)

#### Alternative Name(s)

MND Association, Motor neurone disease (MND), Mndassos, MNDA

#### **Funding Body Type**

Private sector organisation

#### **Funding Body Subtype**

Associations and societies (private and public)

#### Location

United Kingdom

### **Results and Publications**

Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

#### **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	02/06/2015		Yes	No
HRA research summary			28/06/2023		No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes