

Disease biomarkers in amyotrophic lateral sclerosis/motor neuron disease

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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

Primary study design

Interventional

Study design

Multicentre non-randomised interventional diagnosis trial

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	No