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Disease biomarkers in amyotrophic lateral sclerosis/motor neuron disease

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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

Secondary outcome measures
Not provided at time of registration

Overall study start date
24/06/2009

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

Age group
Adult

Sex
Both

Target number of participants
Planned sample size: 100; UK sample size: 100

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
England

United Kingdom

Study participating centre
Institute of Neurology
London
United Kingdom
WC1N 3BG

Sponsor information

Organisation
Barts and The London NHS Trust (UK)

Sponsor details
9 Prescot Street
London
England
United Kingdom
E1 8PR

Sponsor type
Hospital/treatment centre

Website
http://www.bartsandthelondon.nhs.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, MNDA

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

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