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PRION-1: Quinacrine for human prion disease. A partially randomised patient preference trial to evaluate the activity and safety of quinacrine in human prion disease

Submission date
24/02/2004

Registration date
24/03/2004

Last Edited
10/11/2010

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Nervous System Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof John Collinge

Contact details
MRC Prion Unit
Institute of Neurology
National Hospital
Box 59
Queen Square
London
United Kingdom
WC1N 3GB

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00104663

Secondary identifying numbers
G0400713

Study information

Scientific Title

Acronym
PRION-1

Study objectives
The PRION-1 trial is being undertaken to evaluate the activity and safety of quinacrine in human prion disease since there are no other drugs currently available which are considered suitable for human evaluation.

The primary aim of the trial is a randomised controlled comparison of immediate quinacrine treatment versus no quinacrine treatment, with the option of starting quinacrine after 24 weeks (deferred quinacrine); only patients who are willing to be randomised will enter this comparison. However it is appreciated that many patients will have a strong preference for receiving quinacrine immediately. Other patients will have a strong preference for not receiving quinacrine (for example, they may prefer to wait for future therapeutic options). These non-randomised groups of patients will be followed up in the same way as the randomised patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Prion disease (all types)

Interventions
The primary arm of the trial is a randomised controlled comparison of immediate quinacrine treatment (300 mg/day) versus no quinacrine treatment, with the option of starting quinacrine after 24 weeks (deferred quinacrine); only in patients willing to be randomised.
Alternatively, patients can choose to be non-randomised and either receive quinacrine treatment immediately or not receive quinacrine treatment.
PRION-1 is a 3 year trial. It is planned to recruit approximately 160 patients over a period of 2 years and follow all patients for at least 1 year.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Quinacrine

Primary outcome measure
The primary efficacy endpoints are mortality and the proportion of responders overall and at 24 weeks. Response is defined as lack of deterioration in three key neurological and neuropsychiatric measures (standardised neurological exam, a measure of global functioning, and Brief Psychiatric Rating Scale [BPRS]).

Secondary outcome measures
A series of secondary neurological and neuropsychiatric measures (Mini Mental State Examination [MMSE], Clinician's Dementia Rating [CDR], Rankin score, Alzheimers Disease Assessment Scale Cognitive [ADAS-Cog], Glasgow coma score and Barthel Activities of Daily Living [ADL]), and neurological investigations including magnetic resonance imaging scan (MRI), electro-encephalogram (EEG) and cerebro-spinal fluid (CSF) sampling will also be carried out.

Overall study start date
01/05/2004

Completion date
30/04/2007

Eligibility

Key inclusion criteria
Eligible patients will be adults or children aged 12 years or more diagnosed with any type of human prion disease, and without clinical or laboratory abnormalities contraindicating use of quinacrine.

Participant type(s)
Patient

Age group

Adult

Sex
Both

Target number of participants
160

Key exclusion criteria
1. In a coma, or in a pre-terminalphase of disease such that prolongation of the current quality of life would not be supported
2. Have known hypersensitivity to quinacrine
3. Have been taking any other putative anti-prion therapy for less than 8 weeks

Date of first enrolment
01/05/2004

Date of final enrolment
30/04/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
MRC Prion Unit
London
United Kingdom
WC1N 3GB

Sponsor information

Organisation
Medical Research Council (UK)

Sponsor details
Second Floor
Stephenson House
158-160 North Gower St
London
United Kingdom
NW1 2ND

Sponsor type
Research council

ROR
https://ror.org/03x94j517

Funder(s)

Funder type
Government

Funder Name
Department of Health (A861/495)(UK)

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	01/04/2009		Yes	No
Results article	results	01/10/2010		Yes	No