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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

Recruitment status
No longer recruiting

Registration date
24/03/2004

Overall study status
Completed

Last Edited
10/11/2010

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

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00104663

Protocol serial number
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

Study type(s)
Treatment

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(s)
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]).

Key secondary outcome(s))
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.

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

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

Sponsor information

Organisation
Medical Research Council (UK)

ROR
https://ror.org/03x94j517

Funder(s)

Funder type
Government

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

Results and Publications

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