

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	<input checked="" type="checkbox"/> Prospectively registered
Registration date 24/03/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 10/11/2010	Condition category Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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.

Primary study design

Interventional

Study design

Randomised controlled trial

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-terminal phase 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