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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.

### 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-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 |