

An evaluation of potential therapies to inhibit cerebral emboli in dementia

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| Registration date 06/07/2007 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 23/06/2020 | Condition category Mental and Behavioural Disorders | <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

Clinical Trials Information System (CTIS)
2005-004283-23

Protocol serial number
Protocol version 1, EudraCT number: 2005-004283-23

Study information

Scientific Title

An evaluation of potential therapies to inhibit cerebral emboli in dementia

Study objectives

The causes of common dementias such as Alzheimers Disease (AD) and Vascular Dementia (VAD), which affect 800,000 people in the UK, remain uncertain. We recently found that both AD and VAD are associated with small particles (emboli) in the circulation to the brain and that patients with these emboli suffer a more rapid progression of dementia. Prior to major clinical trials on whether therapy to inhibit emboli may prevent or treat dementia, we need to study possible therapies that may inhibit these emboli. We plan to compare two therapeutic approaches:

1. Platelet inhibition
2. An anti-inflammatory lipid therapy thought to stabilise arterial disease

Patients will be given no new treatments. The number of emboli in the cerebral circulation measured by non-invasive ultrasound, assessment of brain function and markers of inflammation associated with dementia will be measured before and after 1 month of the trial treatment. Any treatment or combination of treatments that inhibit cerebral emboli will then be investigated further in major clinical trials on the treatment of established dementia or the prevention of dementia in at risk elderly people.

Ethics approval required

Old ethics approval format

Ethics approval(s)

South Manchester Research Ethics Committee, ref: 05/Q1403/214, Amendment number 1 (06/03/2006)

Study design

Randomised controlled clinical trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Dementia, Alzheimer's disease and Vascular Dementia

Interventions

Randomised controlled clinical trial of atorvastatin/clopidogrel/no treatment over 1 month with crossover in 45 patients with Alzheimer's dementia (AD) and 45 with vascular dementia (VaD)

Patients who are already taking aspirin will continue aspirin therapy. No patient will have therapeutic medication withdrawn.

Those with Spontaneous Cerebral Emboli (SCE) will be randomised, stratified for type of dementia, into one of three counterbalanced treatment orders:

1. Clopidogrel; Atorvastatin; No treatment
2. Atorvastatin; No treatment; Clopidogrel
3. No treatment; Clopidogrel; Atorvastatin

Each treatment will last for 1 month, and there is a washout period of 1 week between each treatment. Transcranial Doppler (TCD) measurement of SCE over two separate 1-hour periods on different days in the same week will be repeated after 4 weeks on each therapy.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Atorvastatin, clopidogrel

Primary outcome(s)

The number of SCE counted during two separate 1-hour periods of monitoring by TCD (at baseline and following each therapy)

Key secondary outcome(s)

1. Any change in the inflammatory markers to Interleukin-6 or C-Reactive Protein as a result of 1 month therapy with the trial medications
2. Any change in the measures of cognitive function as a result of 1 month of therapy using the trial medications

Completion date

30/06/2009

Eligibility**Key inclusion criteria**

1. Dementia: patients must fulfil DSM IV criteria for dementia (Diagnostic and Statistic Manual of Mental Disorders - fourth edition)
2. AD: patients must fulfil the National Institute of Neurological and Communicative Disorders and Stroke-Alzheimer's Disease and Related Disorders Association (NINCDS-ADRDA) criteria
3. VAD: patients must fulfil the National Institute for Neurological and Communicative Disorders and Stroke -Association Internationale pour la Recherche et l'Enseignement en Neurosciences (NINCDS-AIREN) criteria

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Senior

Sex

All

Total final enrolment

33

Key exclusion criteria

1. Patients with a Mini-Mental State Examination (MMSE) score of less than 10 and/or severe aphasia (as the study requires considerable co-operation)
2. Current anticoagulant treatment (may reduce spontaneous emboli)
3. Current clopidogrel treatment
4. Current statin treatment
5. Diagnosed as suffering from Atrial Fibrillation (AF)
6. Diagnosed with significant liver disease: a liver function test will be carried out if liver disease is clinically indicated in any participants
7. Diagnosed with active pathological bleeding such as peptic ulcer or intracranial haemorrhage
8. Any surgery scheduled during study involvement
9. Baseline coagulation parameters suggest unsuitability for clopidogrel/atorvastatin treatment

Date of first enrolment

01/07/2007

Date of final enrolment

30/06/2009

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

University Hospital of South Manchester

Manchester

United Kingdom

M23 9LT

Sponsor information**Organisation**

University Hospital of South Manchester (UK)

ROR

<https://ror.org/00he80998>

Funder(s)

Funder type

Charity

Funder Name

Alzheimer's Society (UK) (grant ref: 87 [30 January 2007])

Alternative Name(s)

alzheimerssoc

Funding Body Type

Private sector organisation

Funding Body Subtype

Associations and societies (private and public)

Location

United Kingdom

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? |
|-------------------------------|---------|--------------|------------|----------------|-----------------|
| Basic results | | | 23/06/2020 | No | No |