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# An evaluation of potential therapies to inhibit cerebral emboli in dementia

| Submission date | Recruitment status |
| --- | --- |
| 05/06/2007 | No longer recruiting |
| **Registration date** | **Overall study status** |
| 06/07/2007 | Completed |
| **Last Edited** | **Condition category** |
| 23/06/2020 | Mental and Behavioural Disorders |

[ ] 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

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

**Protocol serial number**
Protocol version 1, EudraCT number:

## 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)

## Primary study design
Interventional

## Study design
Randomised controlled clinical trial

## 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
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## 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 |