# A pilot study for the VITAL trial (Vitamins and Aspirin for the Treatment of Dementia)

Submission date Recruitment status [ ] Prospectively registered 23/01/2004 No longer recruiting [ ] Protocol [ ] Statistical analysis plan Registration date Overall study status 23/01/2004 Completed [X] Results [ ] Individual participant data **Last Edited** Condition category 31/08/2012 Nervous System Diseases

# Plain English summary of protocol

Not provided at time of registration

# **Contact information**

# Type(s)

Scientific

#### Contact name

Dr Marc Budge

#### Contact details

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# Additional identifiers

EudraCT/CTIS number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers

SPGS773

# Study information

### Scientific Title

### **Acronym**

**VITAL** 

### **Study objectives**

The trial will address the following research objectives:

- 1. Feasibility and practicability of identifying dementia patients from hospital registers and general practice and the validity and acceptability of asking the doctor in charge of such patients to provide diagnostic data using a one page Medical Referral form before the patient attends the study clinic run by specialist nurses.
- 2. Efficacy and acceptability of the 2 methods of assessment of cognitive function, Activities of Daily Living Assessment and evaluation of the response rate to an invitation to attend a screening visit, enter run-in, agree to be randomised and attend a follow-up visit and comply with instructions to take the study treatments.
- 3. Evaluation of the absorption and biochemical effects of aspirin, vitamins E and C, and folic acid and vitamin B12 on markers of platelet function and oxidative damage and on blood vitamin and homocysteine levels when administered alone or in combination in patients with dementia.

### 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

# Secondary study design

Randomised controlled trial

# Study setting(s)

Not specified

# Study type(s)

Treatment

### Participant information sheet

# Health condition(s) or problem(s) studied

Nervous system diseases: Dementia

### **Interventions**

- 1. Aspirin 75 mg or placebo
- 2. Vitamin E (600 mg) and Vitamin C (250 mg) or placebo
- 3. Folic acid (2 mg) and Vitamin B-12 (1 mg) or placebo

### **Intervention Type**

Other

#### Phase

Not Applicable

### Primary outcome measure

The pilot study will determine the feasibility and practicability of the procedures required for recruitment and monitoring of the effects of aspirin and vitamin supplements in a clinical trial in patients with dementia. It will determine the response rates to a request to attend screening, randomisation and follow up visits and compliance with instructions to take study medication. The study will evaluate two alternative methods of assessing cognitive function and evaluate the validity of obtaining medical information on prior vascular disease and current medication about patient from carers. Information gained will guide the choice of treatment to be adopted in a large trial to assess whether such treatments may delay the requirement for institutionalisation in this population.

## Secondary outcome measures

Not provided at time of registration

# Overall study start date

01/06/1999

# Completion date

31/05/2000

# **Eligibility**

# Key inclusion criteria

Male and female patients of all ages with a clinical diagnosis of dementia (according to Diagnostic and Statistical Manual of Mental Disorders, Fourth edition [DSM IV] criteria) of mild to moderate severity will be eligible to participate.

Concomitant therapy prescribed to affect cognitive function (e.g. Donepezil etc.) will be permitted provided the participant has been taking it for at least 3 months before the screening visit and intends to continue taking it for the duration of the VITAL treatment period.

# Participant type(s)

**Patient** 

### Age group

Adult

#### Sex

Both

# Target number of participants

Not provided at time of registration

### Key exclusion criteria

Not provided at time of registration

### Date of first enrolment

01/06/1999

#### Date of final enrolment

31/05/2000

# Locations

### Countries of recruitment

England

**United Kingdom** 

# Study participating centre Department of Pharmacology

Oxford United Kingdom OX2 6HE

# Sponsor information

### Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

### Sponsor details

The Department of Health Richmond House 79 Whitehall London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

### Sponsor type

Government

#### Website

http://www.doh.gov.uk

# Funder(s)

# Funder type

Government

### Funder Name

NHS Executive South East (UK)

# **Results and Publications**

# Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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	01/07/2003		Yes	No