

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Marc Budge

Contact details
Department of Pharmacology
Radcliffe Infirmary NHS Trust
Woodstock Road
Oxford
United Kingdom
OX2 6HE
+44 (0)1865 224356

Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s))

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre
Department of Pharmacology
Oxford
United Kingdom
OX2 6HE

Sponsor information

Organisation

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

Funder(s)

Funder type

Government

Funder Name

NHS Executive South East (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	01/07/2003		Yes	No