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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
Registration date	**Overall study status**	[ ] Statistical analysis plan
23/01/2004	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
31/08/2012	Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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