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Trial of Homocysteine Reduction In the prevention of Vascular Events and Dementia in the elderly

Submission date	Recruitment status	[_] Prospectively registered
12/09/2002	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/09/2002	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
05/01/2011	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
112/57

Study information

Scientific Title

Acronym
THRIVED

Study objectives
1. What are the effects of vitamin combinations (comprising of folic acid plus B12, B6 and B2, each alone and in combination) on serum homocysteine (HCY) in elderly patients with vascular disease?
2. Is telephone follow-up of cognitive function and of disability practicable in this cohort of patients?

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
Ischaemic vascular disease

Interventions
Patients will receive vitamin folic acid (2 mg) plus vitamin B12 (400 mg) or placebo, vitamin B6 (25 mg) or placebo, and B2 (25 mg), in a factorial 2 by 2 design.

Intervention Type
Supplement

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Folic acid, Vitamins B12, B6 and B2

Primary outcome(s)
1. Serum HCY, plasma von Willebrand factor, vitamin levels (red cell folate, serum vitamin B12, B2 and B6)
2. Piloting of telephone follow-up of cognition (Telephone Interview for Cognitive Status [TICSm]) and of disability (Barthel Index and short Instrumental Activities for Daily Living [ADL] scale)

Key secondary outcome(s))

Not provided at time of registration

Completion date
30/11/2003

Eligibility

Key inclusion criteria
1. Age greater than 65 years
2. Ischaemic vascular disease (at least one of the following: history of angina pectoris, acute myocardial infarction, evidence of major ischaemia or previous infarction on 12-lead electrocardiogram, ischaemic stroke, transient ischaemic attack, intermittent claudication, previous surgery for ischaemic vascular disease)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
Not Specified

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/12/2001

Date of final enrolment
30/11/2003

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Academic Section of Geriatric Medicine
Glasgow
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Sponsor information

Organisation
The Health Foundation (UK)

ROR
https://ror.org/02bzj4420

Funder(s)

Funder type
Charity

Funder Name
The Health Foundation (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	01/12/2005		Yes	No