ISRCTN07337345 https://doi.org/10.1186/ISRCTN07337345

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr David J Stott

Contact details
Academic Section of Geriatric Medicine
3rd Floor Centre Block
Glasgow Royal Infirmary
Glasgow
United Kingdom
G4 0SF
+44 (0)141 211 4976
d.j.stott@clinmed.gla.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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)

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/12/2001

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

Age group
Senior

Sex
Not Specified

Target number of participants
100 elderly patients from Glasgow Royal Infirmary

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
Scotland

United Kingdom

Study participating centre
Academic Section of Geriatric Medicine
Glasgow
United Kingdom
G4 0SF

Sponsor information

Organisation
The Health Foundation (UK)

Sponsor details
90 Long Acre
London
United Kingdom
WC2E 9RA
+44 (0)20 7257 8000
info@health.org.uk

Sponsor type
Charity

Website
http://www.pppfoundation.org.uk/

ROR
https://ror.org/02bzj4420

Funder(s)

Funder type
Charity

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