

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/09/2002	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 05/01/2011	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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 [TICS_m]) 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