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A multi-centre, randomised, double-blind, placebo controlled clinical trial examining the efficiency and safety of multi-vitamin therapy in secondary stroke prevention

Submission date 22/05/2003	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 22/05/2003	**Overall study status** Completed	
Last Edited 11/07/2014	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Study website
http://vitatops.highway1.com.au/index.htm

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00097669

Secondary identifying numbers
G0200583

Study information

Scientific Title

Acronym
VITATOPS

Study objectives
To determine whether the addition of vitamin supplement (folate 2 mg, B6 25 mg, B12 500 µg) to best medical/surgical management (including modification of risk factors) will reduce the combined incidence of recurrent vascular events (stroke, myocardial infraction) and vascular death in patients with recent stroke or transient ischaemic attach (TIA).

Secondary objectives:
1. To determine whether the addition of vitamin supplements (folate 2 mg, B6 25 mg, B12 500 µg) will reduce:

a) The incidence of revascularisation procedures of the coronary, cerebral and peripheral circulations

b) Incidence of dementia and depression in patient with recent stroke or TIA

c) Occurrence of TIA in patients with recent stroke or TIA

2. To determine whether the effect of adding vitamin supplements (folate 2 mg, B6 25 mg, B12 500 µg) on the incidence of the primary outcome event (stroke, MI or vascular death) is consistent in patient subgroups such as those of different ethnicity and genotype.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Multicentre randomised double-blind placebo-controlled clinical

Primary study design
Interventional

Secondary study design

Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet
Patient information can be found at: http://vitatops.highway1.com.au/html/index.asp?section=gen

Health condition(s) or problem(s) studied
Cardiovascular

Interventions
Multivitamins folate 2 mg, B6 25 mg, B12 500 µg or placebo

Intervention Type
Supplement

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Multivitamins folate, B6, B12

Primary outcome measure
The primary outcome event is the composite event 'stroke, myocardial infarction, or death from any vascular cause', whichever occurs first.

Secondary outcome measures
Secondary outcome measures include TIA, depression, dementia, unstable angina, revascularisation procedures of the coronary, cerebral and peripheral circulations.

Overall study start date
01/07/2003

Completion date
31/07/2010

Eligibility

Key inclusion criteria
All patients presenting to one of the participating neurologists or general physicians within 7 months of stroke (ischaemic or haemorrhagic) or transient ischemic attack (TIA) (eye or brain) are eligible for this trial.

In addition the patient must:
1. Agree to take study medications

2. Be geographically accessible for follow up
3. Provide written informed consent

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
8000 Added 07/07/2009: UK sample size is 1000 patients.

Key exclusion criteria
1. Taking folate or vitamin B6, on medical advice
2. Use of vitamin supplements containing B6, B12 or Folate (unless patient agrees to take study medication instead of the vitamin supplements which they usually take)
3. Taking Methotrexate for any reason
4. Pregnancy or women of child-bearing potential who are at risk of pregnancy
5. Limited life expectancy

Date of first enrolment
01/07/2003

Date of final enrolment
31/07/2010

Locations

Countries of recruitment
Australia

Austria

Belgium

Brazil

Georgia

Hong Kong

India

Italy

Malaysia

Moldova

Netherlands

New Zealand

Pakistan

Philippines

Portugal

Scotland

Serbia

Singapore

Sri Lanka

United Kingdom

United States of America

Study participating centre
Department of Medicine & Therapeutics
Glasgow
United Kingdom
G11 6NT

Sponsor information

Organisation
University of Glasgow and Greater Glasgow Health Board (UK)

Sponsor details
University of Glasgow
Glasgow
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G12 8QQ
+44 (0)141 330 2000

Sponsor type
Not defined

Website
http://www.gla.ac.uk/

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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?
Protocol article	protocol	01/04/2002		Yes	No
Results article	results	01/09/2010		Yes	No
Results article	cancer sub-study results	01/06/2012		Yes	No
Results article	results	01/06/2012		Yes	No

Results article	MRI sub-study results	01/12/2012	Yes	No
Other publications	secondary analysis	01/08/2013	Yes	No
Results article	osteoporotic fractures sub-study results	03/09/2013	Yes	No