

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

<b>Submission date</b> 22/05/2003	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 22/05/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 11/07/2014	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## 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

### Contact name

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### Contact details

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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 attack (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

United Kingdom

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?
<a href="#">Protocol article</a>	protocol	01/04/2002		Yes	No
<a href="#">Results article</a>	results	01/09/2010		Yes	No
<a href="#">Results article</a>	cancer sub-study results	01/06/2012		Yes	No
<a href="#">Results article</a>	results	01/06/2012		Yes	No

<a href="#">Results article</a>	MRI sub-study results	01/12/2012	Yes	No
<a href="#">Other publications</a>	secondary analysis	01/08/2013	Yes	No
<a href="#">Results article</a>	osteoporotic fractures sub-study results	03/09/2013	Yes	No