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Vitamin K to improve markers of vascular health and physical function in older people with vascular disease

Submission date
04/03/2011

Recruitment status
No longer recruiting

Registration date
28/03/2011

Overall study status
Completed

Last Edited
22/08/2017

Condition category
Circulatory System

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Low intake of vitamin K in the diet has been linked to a higher risk of heart attacks and strokes. This may be because vitamin K is important in keeping blood vessels in good health; low levels of vitamin K are associated with stiffer blood vessels and deposits of calcium in the blood vessel wall. Vitamin K may also be important in keeping nerves working well which are important in maintaining balance and avoiding falls. It is not known whether taking extra vitamin K (as a tablet) can improve balance or blood vessel health, so the aim of this study is to test whether taking a vitamin K tablet for 6 months improves blood vessel health and improves balance in older people who have had (or are at risk of) a heart attack or stroke.

Who can participate?
Older people aged 70 and over who have had (or are at risk of) a heart attack or stroke

What does the study involve?
Participants are randomly allocated to take either vitamin K or a matching placebo (dummy) tablet once a day for 6 months. They are then followed up to assess their blood vessel health and balance.

What are the possible benefits and risks of participating?
If vitamin K improves blood vessel health, it might reduce the risk of heart attacks and strokes, but this study is too small to show this directly. Vitamin K is safe with no known side effects. It can interfere with the action of the drug warfarin, which is why patients on warfarin are excluded from the study.

Where is the study run from?
Ninewells Hospital (UK)

When is the study starting and how long is it expected to run for?
August 2011 to March 2013

Who is funding the study?
Chest Heart and Stroke Scotland (UK)

Who is the main contact?
Dr Miles Witham
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
R11/A137

Study information

Scientific Title
Vitamin K to improve markers of vascular health and physical function in older people with vascular disease: a randomised controlled trial

Acronym
KIMVASC

Study objectives
To test whether vitamin K supplementation improves markers of vascular health in older people with vascular disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East of Scotland NHS Research Ethics Committee, 12/09/2011, ref: 11/ES/0009

Primary study design
Interventional

Study design
Parallel-group double-blind placebo-controlled randomised trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Vascular disease

Interventions
Vitamin K2 (MK7 subtype) 100 mcg per day or placebo.

Added 18/08/2017:
Participants are randomised to take either:
1. Vitamin K2 (MK7 subtype) given as 100 mcg oral tablet once a day for 6 months
2. Matching placebo tablet, given once a day for 6 months
Treatment in both arms given for 6 months, which is also the length of follow up.

Intervention Type
Supplement

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Vitamin K

Primary outcome(s)
Flow-mediated dilatation of the brachial artery measured at baseline and 6 months

Key secondary outcome(s)
Measured at baseline, 3 months and 6 months:
1. Markers of vascular function:
1.1. Arterial stiffness and reflectivity, measured using pulse wave velocity and augmentation index
1.2. Carotid intima-media thickness and compliance
2. Markers of vascular prognosis: brain natriuretic peptide (BNP), office blood pressure (BP) (lying and standing), total cholesterol, high density lipoprotein (HDL) cholesterol, low density lipoprotein (LDL) cholesterol
3. Markers of inflammation: high-sensitivity C-reactive protein
4. Serum MK7 levels, measured by high-performance liquid chromatography (HPLC)
5. Markers of physical function:
5.1. Short Physical Performance Battery; predicts disability, falls and death
5.2. Balance, measured using force plate analysis
5.3. Grip strength as a test of maximal muscle strength; predicts institutionalisation and death

Completion date
31/03/2013

Eligibility

Key inclusion criteria
1. Aged 70 and over
2. At least one of the conditions:
2.1. Hypertension (based on recorded diagnosis from primary or secondary care)
2.2. Diabetes mellitus (based on recorded diagnosis from primary or secondary care)
3. Established vascular disease: myocardial infarction [based on symptoms of ischaemia or electrocardiogram (ECG) changes, plus rise in cardiac enzymes]
4. Percutaneous transluminal coronary angioplasty
5. Coronary artery bypass grafting
6. Stroke/transient ischaemic attack (TIA) (diagnosis established in secondary care)
7. Peripheral vascular disease (symptoms of peripheral ischaemia and either a previous ankle /brachial pressure index < 0.7 or previous evidence of arterial stenosis on angiography or ultrasound)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Key exclusion criteria
1. Atrial fibrillation
2. Taking warfarin
3. Unable to give written informed consent
4. Unable to walk without human assistance (walking aids are permitted)

Date of first enrolment
01/09/2011

Date of final enrolment
30/09/2012

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Ninewells Hospital
Dundee
United Kingdom
DD1 9SY

Sponsor information

Organisation
Tayside Academic Sciences Collaboration (UK)

ROR
https://ror.org/049x86d03

Funder(s)

Funder type
Charity

Funder Name
Chest Heart and Stroke Scotland (ref: R11/A137)

Alternative Name(s)
Chest Heart & Stroke Scotland, CHSScotland, CHSS

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available upon request from Dr Miles Witham (m.witham@dundee.ac.uk). Anonymised individual participant data on all those randomised will be made available to bona fide researchers for non-commercial use, subject to sight of an analysis plan and subject to appropriate data sharing agreements and approval from the trial Sponsor.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2016		Yes	No
Basic results		04/08/2017	22/08/2017	No	No