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Using vitamin K to improve strength and balance in older people

Submission date	Recruitment status	[X] Prospectively registered
30/09/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/10/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
20/08/2021	Signs and Symptoms	

Plain English summary of protocol

Background and study aims
Vitamin K plays a vital role in the body by helping blood to clot and preventing excessive bleeding. It typically comes in two forms: vitamin K1, which is found in leafy green vegetables and vitamin K2, which is found in meat, eggs and cheese. Recent studies have shown that vitamin K2 can help to keep bones healthy and may help to prevent muscle weakness. Falls are one of the leading causes of death and injury in people over the age of 65. Although falls can occur for a variety of reasons, balance problems are thought to play an important role. The aim of this trial is to find out whether vitamin K2 supplements can help to improve balance and reduce the risk of falls in older people.

Who can participate?
Adults aged 65 or over with a history of falls over the last year.

What does the study involve?
Participants are randomly allocated into three groups. The first group take a 400mcg vitamin K2 tablet once a day for 12 months; the second group take a 200mcg vitamin K2 tablet once a day for 12 months and the third group take a placebo tablet (dummy pill) once a day for 12 months. At the end of the 12 months, the balance of all participants is measured at a follow-up appointment by seeing the amount that they sway forwards and backwards on a balance board. At this appointment, participants also have a sample of blood taken to measure the effect of vitamin K in the body as well as having their blood pressure tested while standing up and how well their legs are functioning. They are also asked to provide information about their contact with the health service over the past year.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
1. NHS Tayside (UK)
2. NHS Grampian (UK)
3. NHS Fife (UK)

When is the study starting and how long is it expected to run for?
September 2015 to September 2018

Who is funding the study?
Chief Scientist Office (UK)

Who is the main contact?
Dr Miles Witham

Contact information

Type(s)
Public

Contact name
Dr Miles Witham

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2013GR09

Study information

Scientific Title
Vitamin K therapy to reduce falls – a pilot randomised controlled trial

Acronym
K-SWAY

Study objectives
Main objective:
To test which dose of oral vitamin K2 (200 mcg or 400 mcg once daily for 1 year) most improves anteroposterior sway compared to placebo.

Secondary objectives:
1. To test whether 1 year of vitamin K2 supplementation (200 mcg or 400 mcg per day) improves markers of balance, lower limb function and postural blood pressure
2. To test whether 1 year of vitamin K2 supplementation (200 mcg or 400 mcg per day) reduces falls
3. To assess whether use of oral K2 supplementation (200 mcg or 400 mcg per day) is associated with a reduction in health and social care utilisation

Ethics approval required
Old ethics approval format

Ethics approval(s)
East of Scotland Research Ethics Committee, 15/12/2015, approval number: 15/ES/0197

Study design
Multi-centre randomised placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Prevention

Participant information sheet
Not available in web format; please use contact details below to request a participant information sheet

Health condition(s) or problem(s) studied
Prevention of falls and loss of balance in older people

Interventions
Participants are randomly allocated into one of three groups:
Group 1: Receive a daily oral dosing of 400 mcg vitamin K2 (MK7 subtype) for a period of 12 months
Group 2: Receive a daily oral 200 mcg vitamin K2 (MK7 subtype) for a period of 12 months
Group 3: Receive a daily oral dose of a placebo for a period of 12 months

Intervention Type
Supplement

Primary outcome measure
Difference in anterior-posterior sway measured using a balance platform at baseline and 12 months.

Secondary outcome measures
1. Additional markers of postural sway (mediolateral sway, 95% ellipse, RMS, total path length) measured using the AMTI sway meter at baseline, 6 and 12 months
2. Berg balance scale compared between groups at baseline, 6 and 12 months
3. Postural blood pressure drop on standing measured at baseline, 1 and 3 minutes after standing at 6 and 12 months
4. Vitamin K levels are determined by measuring dp-ucMGP levels in the blood at baseline and 12 months
5. Physical function determined with a short physical performance battery, timed up and go test at each time point at baseline, 6 and 12 months
6. Falls frequency determined from monthly falls diary to prospectively record falls
7. Health and social care utilisation data collected using a healthcare data and patient questionnaire at baseline, 6 and 12 months

Overall study start date
01/09/2015

Completion date
30/09/2018

Eligibility

Key inclusion criteria
1. Aged 65 years or over
2. Two or more self-reported falls in the previous 12 months OR at least one fall resulting in hospitalisation in the previous 12 months
3. Able (in the Investigators opinion) and willing to comply with all study requirements.

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
96

Total final enrolment
95

Key exclusion criteria
1. Unable to give written informed consent
2. Unable to stand without human assistance
3. Atrial fibrillation (as this group should usually be taking warfarin)
4. Taking warfarin (which antagonises vitamin K) or other coumadin derivatives
5. Taking vitamin K supplements
6. Known contraindication to Vitamin K

7. Currently enrolled in another trial (other than observational trials and registries), or within 30 days of completing another trial
8. Currently undertaking physiotherapy or another time-limited supervised non-pharmacological intervention to reduce falls risk
9. Intolerance to soya products

Date of first enrolment
01/04/2016

Date of final enrolment
31/01/2017

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
NHS Tayside
Ninewells Hospital
Dundee
United Kingdom
DD1 9SY

Study participating centre
NHS Grampian
Aberdeen Royal Infirmary
Aberdeen
United Kingdom
AB25 2ZN

Study participating centre
NHS Fife
Victoria Hospital
Kirkcaldy
United Kingdom
KY2 5AH

Sponsor information

Organisation
Tayside Academic Science Centre (UK)

Sponsor details
TASC Research & Development Office
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Sponsor type
University/education

ROR
https://ror.org/049x86d03

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office

Alternative Name(s)
CSO

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Publication and dissemination plan

Main trial results will be published within 12 months of end of trial, via report to funder (CSO, Scottish Government) and in peer-reviewed journal. Results will also be disseminated to participants and their families via a brief written summary and via presentation at study tea-parties.

Intention to publish date
01/09/2019

Individual participant data (IPD) sharing plan
Participant level, anonymised data will be available for sharing with bona-fide academic groups, subject to submission and approval of an analysis plan by a data access committee led by the Sponsor. Please contact Professor Witham or the Sponsor (TASCgovernance@dundee.ac.uk) to discuss proposals for data sharing.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		14/01/2018	14/01/2019	No	No
Results article	Results of study within a trial (SWAT) comparing two participant information sheets	01/12/2018	08/10/2019	Yes	No
Results article		18/06/2019	20/08/2021	Yes	No
HRA research summary			28/06/2023	No	No