

# Using vitamin K to improve strength and balance in older people

<b>Submission date</b> 30/09/2015	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 05/10/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 20/08/2021	<b>Condition category</b> Signs and Symptoms	<input type="checkbox"/> Individual participant data

## 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?
<a href="#">Basic results</a>	Results of study within a trial (SWAT) comparing two participant information sheets	14/01/2018	14/01/2019	No	No
<a href="#">Results article</a>		01/12/2018	08/10/2019	Yes	No
<a href="#">Results article</a>		18/06/2019	20/08/2021	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No