Scottish Government Health Directorates Chief Scientist Office

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Vitamin K therapy to reduce falls – a pilot randomised controlled trial (CZH/4/1100)

Researchers
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Aim
To perform a pilot randomised controlled trial, testing two doses of vitamin K2 as a way to improve postural sway and reduce falls in older people at risk of falls.

Project Outline/Methodology
We conducted a double blind, randomised, placebo controlled trial. Participants aged 65 and over with two or more falls in the last year were recruited via primary care mailshots and assessed at 3 centres in Scotland (Grampian, Tayside and Fife). Participants were randomised to receive once daily placebo (dummy) tablets, 200mcg or 400mcg of vitamin K2 for 1 year. Outcomes were measured at baseline, six and twelve months.

The primary outcome was forwards/backwards sway measured standing on a sway plate. Secondary outcomes included falls, lower limb physical performance tests and a range of balance tests. We collected information on the rate of recruitment at each site and also the rate of dropout from the trial. We also conducted a health economic analysis to estimate healthcare costs in each group, assess quality-adjusted life years, and estimate whether it would be economically worthwhile to spend money on a larger trial of vitamin K for falls.

Key Results
We aimed to recruit 96 participants and finished the trial with 95 recruits. We recruited 3 participants per centre per month on average. Fewer people dropped out over the year than we expected (81% attended the 12 month visit compared to our prediction of 66%). Vitamin K was well tolerated with similar levels of adverse events in each group.

We found no effect of vitamin K on forwards/backwards sway, physical performance, or other balance tests. Rates of falls in each group were similar, although the trial was not designed to be large enough to detect small differences in falls rates. Costs were higher in the vitamin K groups (£287 to £297 for 200mcg vitamin K; £43 to 57 for 400mcg vitamin K) than for the placebo group. No significant benefit was seen on quality adjusted life years, but the small size of the trial means that an effect cannot be excluded.

An estimate of the economic viability of doing a larger trial (the Expected Value of Sample Information) suggested that the most economically efficient trial would have 130 participants in each arm, but that a trial of up to 1000 participants in each arm would still be economically viable if other evidence supported doing such a trial.

Conclusions
Recruitment and retention were acceptable in this pilot trial, but vitamin K2 supplementation did not improve postural sway, falls or physical function in older people at risk of falls. Conducting a full trial would be economically viable if fewer than 1000 participants per group were required.

What does this study add to the field?
This is the first trial where vitamin K has been tested as a way of reducing falls in older people at risk of falls. The results however do not support using vitamin K for this purpose at present.

Implications for Practice or Policy
Although vitamin K is a cheap and safe intervention, it does not have a place in practice to prevent falls at present. Other trials testing vitamin K for other conditions, for example vascular disease, are still ongoing.

Where to next?
The results from this trial do not support progressing to a larger trial at this point. Instead, we await the findings from other trials using vitamin K and will aim to combine these in a systematic review

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