

A randomised double-blind placebo-controlled trial of the effect of vitamin and mineral supplements on morbidity from infections in men and women over 65 years

Submission date 05/10/2001	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 05/10/2001	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 07/04/2010	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Study website

<http://www.abdn.ac.uk/hsru/hta/mavis.shtml>

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

Secondary identifying numbers

None

Study information

Scientific Title

Acronym

MAVIS (Mineral and Vitamin Intervention Trial)

Study objectives

Infections are common in older people. The vitamin and mineral status of many older people may be sub-optimal, influencing immunity and risk of infection. We examined whether vitamin and mineral supplementation influences self-reported infections, health service use, quality of life and is cost-effective in people aged 65 years and older, over one year. The MAVIS trial was a randomised, placebo-controlled trial, with blinding of participants, outcome assessors and investigators until analyses were completed.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Prevention

Participant information sheet

Health condition(s) or problem(s) studied

Mineral & vitamin supplementation

Interventions

Daily vitamin and mineral supplement, approximating the Reference Nutrient Intake (RNI) of 11 vitamins and five minerals, or a matching placebo in a double blind design for 1 year

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Primary care contacts
2. Self-reported days of infection
3. Quality of life

Secondary outcome measures

Antibiotic prescriptions, hospital admissions, adverse events, health service costs and compliance.

Overall study start date

01/08/2001

Completion date

31/07/2004

Eligibility

Key inclusion criteria

Men and women over 65 years

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

910

Key exclusion criteria

People too unwell to take part

Date of first enrolment

01/08/2001

Date of final enrolment

31/07/2004

Locations

Countries of recruitment

Scotland

United Kingdom

Study participating centre

Clinical Research Fellow University of Aberdeen

Aberdeen

United Kingdom

AB25 2ZD

Sponsor information

Organisation

Health Services Research Unit, University of Aberdeen (UK)

Sponsor details

Polwarth Building

Foresterhill

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Scotland

United Kingdom

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Sponsor type

University/education

ROR

<https://ror.org/016476m91>

Funder(s)

Funder type

Charity

Funder Name

The Health Foundation (UK)

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?
Results article	results	06/08/2005		Yes	No
Results article	results	02/05/2007		Yes	No
Results article	results	01/01/2010		Yes	No