ISRCTN66376460 https://doi.org/10.1186/ISRCTN66376460

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

Registration date
05/10/2001

Overall study status
Completed

Last Edited
07/04/2010

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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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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
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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