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Mechanisms by which fruit and vegetables influence postmenopausal bone health: a randomised controlled trial in a well-characterised population

Submission date
04/04/2007

Recruitment status
No longer recruiting

Registration date
30/04/2007

Overall study status
Completed

Last Edited
03/05/2011

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
FSA project number: N05043

Study information

Scientific Title

Acronym
ADAFVT (Aberdeen Dietary Acidity, Fruit and Vegetable Trial)

Study objectives
To test whether fruit and vegetable intake reduces the acidity of a mixed diet and the requirement of bone for buffering, or provide other dietary components important for bone health.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Grampian Research Ethics Committee on 23/12/2002 (ref: 02/0053).

Study design
Two year placebo-controlled randomised trial (double blind for potassium citrate arms and single blind for fruit and vegetable arm).

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Low bone mass/risk of osteoporosis

Interventions
Minimisation criteria included key genotypes (vitamin D receptor genotype and Apolipoprotein E genotype, smoking and dietary acidity (calculated from protein to potassium ratio).

Group A: potassium citrate equivalent to 900 g fruit and vegetables (55.5 mEq)
Group B: potassium citrate equivalent to 300 g fruit and vegetables (18.5 mEq)
Group C: 300 g of fruit and vegetables
Group D: placebo

Duration of treatment was two years for each treatment arm.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)

1. Bone turnover markers:
a. serum N-terminal Propeptide of type 1 collagen (P1NP), measured at baseline, 3, 6, 12, 18 and 24 months
b. serum C-terminal telopeptide of type I collagen (CTX), measured at baseline, 3, 6, 12, 18 and 24 months
c. urinary free Deoxypyridinoline cross-links (fDPD), measured at baseline, 3, 6, 12, 18 and 24 months; women also posted a fasted urine sample 6 to 8 weeks after the baseline visit

Key secondary outcome(s))
Bone mineral density change over two years measured by DEXA at baseline and 24 months.

Completion date
01/12/2005

Eligibility

Key inclusion criteria
Women aged 55 years to 65 years who had taken part in a longitudinal study (Aberdeen Prospective Osteoporosis Screening Study). Includes:
1. Otherwise healthy women taking other types of diuretics (not potassium sparing diuretics) or hypertension tablets
2. Women on thyroxine treatment provided their thyroid function is stable (as assessed by free Thyroxine [T4] and Thyroid Stimulating Hormone [TSH] levels) and their dose had not changed in the year prior to study entry

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Suffering from severe disease
2. Malabsorption
3. Having difficulties swallowing tablets/capsules
4. Taking oral corticosteroids
5. On or past bisphosphonate treatment (more than a few weeks)
6. Taking Hormone Replacement Therapy (HRT) in the last six months
7. Less than five years past the menopause
8. Currently taking potassium-sparing diuretics
9. Osteoporosis diagnosed from Dual Energy X-ray Absorptiometry (DEXA) scan at baseline visit

Date of first enrolment
01/03/2003

Date of final enrolment
01/12/2005

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Osteoporosis Research Unit
Aberdeen
United Kingdom
AB25 2ZD

Sponsor information

Organisation
Food Standards Agency (UK)

ROR
https://ror.org/05p20a626

Funder(s)

Funder type
Government

Funder Name
Food Standards Agency (UK)

Alternative Name(s)
The Food Standards Agency, FSA

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location

United Kingdom

Results and Publications

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	01/08/2008		Yes	No