

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	☐ Prospectively registered
Registration date 30/04/2007	Overall study status Completed	☐ Protocol
Last Edited 03/05/2011	Condition category Musculoskeletal Diseases	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Helen Macdonald

Contact details

Osteoporosis Research Unit
Health Sciences Building
University of Aberdeen
Osteoporosis Research Unit
Foresterhill
Aberdeen
United Kingdom
AB25 2ZD
+44 (0)1224 559001
h.macdonald@abdn.ac.uk

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).

Primary study design

Interventional

Study design

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

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

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