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Investigating the effect of vitamin K supplementation on markers of bone turnover and bone density in adolescents and adults with cystic fibrosis

Submission date
02/04/2008

Recruitment status
No longer recruiting

Registration date
09/05/2008

Overall study status
Completed

Last Edited
27/04/2016

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

vit K 2006

Study information

Scientific Title
Investigating the effect of vitamin K supplementation on markers of bone turnover and bone density in adolescents and adults with cystic fibrosis

Study objectives
Vitamin K supplementation improves markers of bone turnover and bone density in adolescents and adults with cystic fibrosis (CF).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Wandsworth Research Ethics Committee, 11/08/2006 (protocol v4), 18/05/2007 (amendments protocol v5) and 03/08/2007 (amendments protocol v6).

Study design
Randomised double-blind placebo-controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Bone health in cystic fibrosis

Interventions
1. 10 mg of menadiol phosphate (water soluble form of vitamin K) once daily (o.d.) orally for 12 months
2. Matching placebo for 12 months

Total duration of treatment and follow-up: 12 months for both arms.

Intervention Type
Supplement

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Vitamin K supplementation

Primary outcome measure
The between-groups difference in the ratio of undercarboxylated osteocalcin to total osteocalcin, measured prior to supplementation starting and at the end of the 12 months supplementation.

Secondary outcome measures
The between-group differences in:
1. Total osteocalcin
2. Undercarboxylated osteocalcin
3. N Terminal X (marker of bone resorption)
4. Bone specific alkaline phosphatase
5. Serum vitamin D
6. Calcium
7. Dual energy x-ray absorptiometry (DEXA) scan z and t scores of lumbar spine and femoral neck (scores adjusted for age, height and sex)

Measured prior to supplementation starting and at the end of the 12 months supplementation.

Overall study start date
02/01/2007

Completion date
09/02/2009

Eligibility

Key inclusion criteria
1. Patients with a diagnosis of CF (positive sweat test or genotype testing)
2. Patients aged greater than 16 years (post pubertal-stage IV Tanner), either sex
3. Patients are pancreatic insufficient (i.e. with a positive faecal elastase test, and requiring pancreatic enzyme supplementation)
4. No evidence of overt liver disease (not on ursodeoxycholic acid)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Patients already taking vitamin K supplementation
2. Patients with osteoporosis or osteopaenia and taking bisphosphonates
3. Patients with abnormally low vitamin D levels (less than 30 µg)
4. Patients on maintenance oral corticosteroids
5. Patients who are considered to have very sedentary lifestyle or follow a rigorous exercise training programme
6. Patients with overt liver disease
7. Patients who do not consent to participate
8. Patients with a life expectancy of less than 12 months
9. Patients who are non-compliant with maintenance therapies

Date of first enrolment
02/01/2007

Date of final enrolment
09/02/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Respiratory Medicine
London
United Kingdom
E2 9JX

Sponsor information

Organisation
Barts and the London NHS Trust (UK)

Sponsor details
Research and Development Department
24 - 26 Walden Street
Whitechapel
London
England
United Kingdom
E1 2AN

Sponsor type
Hospital/treatment centre

Website
http://www.bartsandthelondon.org.uk/

ROR
https://ror.org/00b31g692

Funder(s)

Funder type
Government

Funder Name
Barts and the London NHS Trust (UK) - Internally funded from Nursing, Midwifering and Allied Health Profession research grant

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