

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

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<b>Registration date</b> 09/05/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 27/04/2016	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## 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

## 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