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# Vitamin K deficiency in the pathogenesis of osteoporosis in primary biliary cirrhosis (PBC)

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 23/01/2004 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 23/01/2004 | Completed | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 13/12/2013 | Musculoskeletal Diseases | [ ] 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**
RBF 98X36

# Study information

## Scientific Title

## Study objectives
To determine the vitamin K status and measure bone mineral density loss over 12 months in 60 patients presenting with primary biliary cirrhosis. To determine the effects of vitamin K therapy on longitudinal bone mineral density and biochemical markers of bone metabolism in primary biliary cirrhosis patients.

## 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)
Hospital

## Study type(s)
Prevention

## Participant information sheet

## Health condition(s) or problem(s) studied
Osteoporosis

## Interventions
i. Vitamin K supplementation
ii. No vitamin K supplementation

## Intervention Type
Supplement

## Phase
Not Specified

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

### Primary outcome measure
Should Vitamin K supplementation be found to alter the course of bone loss in PBC patients it would provide a very cost effective therapeutic intervention. The research may have additional implications for healthcare provision in other areas of metabolic bone disease.

### Secondary outcome measures
Not provided at time of registration

### Overall study start date
01/10/1998

### Completion date
31/03/2003

## Eligibility

### Key inclusion criteria
Sixty out-patients with PBC will be recruited from the Royal Hallamshire Hospital Liver Service.

### Participant type(s)
Patient

### Age group
Not Specified

### Sex
Not Specified

### Target number of participants
60

### Key exclusion criteria
Not provided at time of registration

### Date of first enrolment
01/10/1998

### Date of final enrolment
31/03/2003

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre

**Department of Gastroenterology**
Sheffield
United Kingdom
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# Sponsor information

**Organisation**
NHS R&D Regional Programme Register - Department of Health (UK)

**Sponsor details**
The Department of Health
Richmond House
79 Whitehall
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+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

**Sponsor type**
Government

**Website**
http://www.doh.gov.uk

# Funder(s)

**Funder type**
Government

**Funder Name**
NHS Executive Trent, 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