

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

<b>Submission date</b> 23/01/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 23/01/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 13/12/2013	<b>Condition category</b> Musculoskeletal Diseases	<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**  
Dr Dermot Gleeson

**Contact details**  
Department of Gastroenterology  
Royal Hallamshire Hospital  
Glossop Road  
Sheffield  
United Kingdom  
S10 2JF  
+44 (0)114 271 2832

## Additional identifiers

**Protocol serial number**  
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

**Primary study design**

Interventional

**Study design**

Randomised controlled trial

**Study type(s)**

Prevention

**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(s)**

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.

**Key secondary outcome(s)**

Not provided at time of registration

**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

**Healthy volunteers allowed**

No

**Age group**

Not Specified

**Sex**

Not Specified

**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**

United Kingdom

England

**Study participating centre**

**Department of Gastroenterology**

Sheffield

United Kingdom

S10 2JF

**Sponsor information**

**Organisation**

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

**Funder(s)**

**Funder type**  
Government

**Funder Name**  
NHS Executive Trent, UK

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**  
Not provided at time of registration