ISRCTN34566366 https://doi.org/10.1186/ISRCTN34566366

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

Submission date 23/01/2004	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 23/01/2004	**Overall study status** Completed	
Last Edited 13/12/2013	**Condition category** Musculoskeletal Diseases	

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