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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
S10 2JF

Sponsor information

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

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+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