

Longterm Osteopenia in Crohn's Disease Study: Comparing the affect of Calcium & Vitamin D or additional Sodium-Fluoride or Ibandronate on Bone Mineral Density and Fractures in Crohns Disease

Submission date

09/03/2010

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

14/04/2010

Overall study status

Completed

☐ Statistical analysis plan

☐ Results

Last Edited

14/04/2010

Condition category

Musculoskeletal Diseases

☐ Individual participant data

☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Jochen Klaus

Contact details

Albert Einstein Allee 23

Ulm

Germany

89081

Additional identifiers

Protocol serial number

Osteopenie_01

Study information

Scientific Title

A 3.5 year Randomised Controlled Study on Bone Mineral Density and Fractures in Crohns Disease comparing Calcium & Vitamin D or additional Sodium-Fluoride or Ibandronate

Study objectives

To assess the effect of colecalciferol and calcium administration alone or with additional sodium-fluoride or ibandronate on bone mineral density (BMD) and fracture rate in Crohn's disease patients with reduced bone mineral density

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Ethics Committee of the University of Ulm, Germany approved on the 7th of April 1998 (ref: 281998)

Primary study design

Interventional

Study design

3 arm randomised active controlled parallel group trial

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Crohn's disease, Osteoporosis

Interventions

Patients were randomised to treatment-group A, B and C, taking study-medication as follows:
Group A: 10000 International Units (IU) colecalciferol (Vigantoletten®, Merck, Darmstadt /Germany) and 800mg calcium-citrate (Calcitrat®, Merckle, Ulm/Germany) daily
Group B: 1000IU colecalciferol and 800mg calcium-citrate daily with an additional 25mg of slow-release sodium-fluoride (Nafril®, Merckle, Ulm/Germany) twice daily (bid)
Group C: Basic colecalciferol and calcium with an additional 1mg/IV of ibandronate (Bondronat®, Roche, Basle/Switzerland) 3 times a month

Follow-up examinations were conducted at 3-month intervals. In group B, sodium-fluoride was taken daily for 12-months, followed by a 3-months fluoride-free period. The 2nd and 3rd 12-month cycle started at month 15 and 30.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Dual Energy X-ray Absorptiometry (DEXA) of the lumbar spine and plain radiography of the spine performed at baseline and after 1.0, 2.25 and 3.5 years.

Key secondary outcome(s)

Fracture rate (spine, T4-L4)

Completion date

30/08/2008

Eligibility

Key inclusion criteria

1. Crohn's disease
2. Reduced bone mineral density (T-score < -1,0)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Age <18 years
2. Chronic renal insufficiency (creatinine >1,5mg/dl)
3. Known primary hypo- or hyperparathyroidism
4. Untreated thyroid disease
5. Any known medication, e.g. previous treatment with either sodium-fluoride or bisphosphonates
6. Condition affecting BMD other than glucocorticoids

Date of first enrolment

01/04/1998

Date of final enrolment

30/08/2008

Locations

Countries of recruitment

Germany

Study participating centre

Albert Einstein Allee 23

Ulm

Germany

89081

Sponsor information

Organisation

University Hospital Ulm (Universitätsklinikum Ulm) (Germany)

ROR

<https://ror.org/05emabm63>

Funder(s)

Funder type

University/education

Funder Name

University of Ulm (Germany) - Department of Internal Medicine I, Gastroenterology and Endocrinology

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration