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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	Recruitment status	[ ] Prospectively registered
09/03/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
14/04/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
14/04/2010	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

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)

Study design
3 arm randomised active controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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.

Secondary outcome measures
Fracture rate (spine, T4-L4)

Overall study start date
01/04/1998

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

Age group
Adult

Sex
Both

Target number of participants
200

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)

Sponsor details
Clinic for Internal Medicine I
(Klinik für Innere Medizin I)
Albert-Einstein-Allee 23
Ulm
Germany
89081

Sponsor type
University/education

Website
http://www.uniklinik-ulm.de/struktur/kliniken/innere-medizin/klinik-fuer-innere-medizin-i.html

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

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