

# 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

<b>Submission date</b> 09/03/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 14/04/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 14/04/2010	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<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

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## 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)

### **Study design**

3 arm randomised active controlled parallel group trial

### **Primary study design**

Interventional

### **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