

Treatment of bone loss and changes in bone architecture in osteopenic patients with Crohn's disease: a comparison between calcium supplementation and vitamin D alone or combined with oral risedronate 35 mg once weekly

Submission date 20/12/2005	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 20/12/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 20/08/2021	Condition category Digestive System	☐ Individual participant data

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

N/A

Study information

Scientific Title

Treatment of bone loss and changes in bone architecture in osteopenic patients with Crohn's disease: a comparison between calcium supplementation and vitamin D alone or combined with oral risedronate 35 mg once weekly

Acronym

Crohn and Bone study

Study objectives

Bifosfonates in combination with vitamin D and Calcium is more effective than Vitamin D and Calcium alone for Crohn's disease related osteopenia.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Study design

Randomised, placebo controlled, parallel group, double blinded multicentre trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Crohn's, Osteopenia

Interventions

For both study groups: 1000 mg Calcium and 400 IU vitamin D.

Group I: weekly 35 mg risedronate (Actonel®)

Group II: weekly one placebo tablet

Patients will receive treatment for 24 months.

Intervention Type

Supplement

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Calcium, vitamin D and risedronate (Actonel®)

Primary outcome(s)

The primary objective of this study is to determine the change in BMD, expressed as T-score, at lumbar spine and total hip as assessed by DEXA after 24 months of treatment with Calcium 1 g and vitamin D3 400 IU once daily (o.d.), with concomitant weekly 35 mg risedronate (Actonel®) compared to placebo in patients suffering from Crohns disease.

Key secondary outcome(s)

1. To study the histomorphometric, micro architectural and mineralisation changes in bone after treatment of bone loss in patients with Crohns disease with calcium and vitamin D alone or in combination with risedronate
2. To determine changes in markers of bone metabolism (bone specific alkaline phosphatase, osteocalcine, and type-one collagen C-telopeptide)
3. To establish the incidence of non-vertebral and vertebral fractures, as measured by semi-quantitative assessment of digital, standardised radiographs of the spine

Completion date

31/08/2007

Eligibility**Key inclusion criteria**

1. Men and women between 18 and 70 years of age
2. Patients suffering from Crohn's disease of at least three months duration, confirmed by radiography, endoscopy and histology
3. Quiescent stage of disease as defined by the Crohn's Disease Activity Index (CDAI less than 150)
4. A Bone Mineral Density (BMD) between -1.0 SD and -2.5 SD as assessed by Dual Energy X-ray Absorptiometry (DEXA) (T-score) of lumbar spine or total hip
5. A serum 25(OH)-vitamin D level more than 25 nmol/L
6. Patients must be able to adhere to the study visit schedule and protocol requirements
7. Patients must be able to give informed consent and the consent must be obtained prior to any study procedures

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

1. Patients with a DEXA T-score less than -2.5 in lumbar spine or total hip
2. Patients who have received bisphosphonates a year prior to inclusion, or who are known with an allergy to bisphosphonates
3. Patients who have received calcitonin or suppressive doses of thyroxine within one year

4. Patients with serum 25(OH)-vitamin D levels less than 25 nmol/L (supplementation for three months prior to (renewed) screening is allowed)
5. Corticosteroid treatment three months prior to screening or during the screening phase with daily dosages above 75 mg prednisole-equivalent at any time
6. A history of hyperthyroidism, Paget's disease or other metabolic bone diseases, Cushing's disease or hyperprolactinemia
7. Female patients who are pregnant or breast-feeding
8. Patients receiving hormonal replacement therapy
9. A psychiatric, addictive, or any disorder that compromises ability to give truly informed consent for participation in this study

Date of first enrolment

30/08/2004

Date of final enrolment

31/08/2007

Locations

Countries of recruitment

Netherlands

Study participating centre

IBD trial bureau

Amsterdam

Netherlands

1105 AZ

Sponsor information

Organisation

Aventis (The Netherlands)

ROR

<https://ror.org/00pgqb537>

Funder(s)

Funder type

Industry

Funder Name

Aventis (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		21/10/2013	20/08/2021	Yes	No