

Risedronate for the prevention of bone loss after steroid therapy for a flare-up in inflammatory bowel disease

Submission date 16/11/2008	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 20/11/2008	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 06/10/2011	Condition category Digestive System	☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

2004-004325-10

Protocol serial number

ME/2005/2018; 2004-004325-10

Study information

Scientific Title

A randomised controlled trial to evaluate whether a short course of once weekly risedronate prevents bone loss following high-dose steroid therapy for an acute exacerbation of inflammatory bowel disease

Study objectives

The hypothesis is based on the observation that osteoporosis occurs in patients with inflammatory bowel disease (IBD) and that detectable bone loss occurs after steroid treatment for only 8 weeks. Bisphosphonates are effective at treating bone loss but whether it is effective at preventing bone loss in this context is being addressed in this trial.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Gloucestershire Research Ethics Committee approved the trial in June 2005 (ref: 05/Q2005/74)

Study design

Randomised, double-blind, placebo controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Inflammatory bowel disease (ulcerative colitis and Crohn's disease)

Interventions

All patients participating in the trial were given calcium and vitamin in the form of Cacit D3 effervescent granules (calcium 500 mg/Vitamin D 440IU) at a dose of one sachet daily. Patients were randomised to risedronate 35 mg weekly or a placebo.

The total duration of intervention was 8 weeks and follow up was for the same 8 weeks in both arms. Participants were seen at baseline and then 8 weeks.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Risedronate

Primary outcome(s)

The difference in percentage change in total hip (and sub-regions of the hip) and lumbar spine bone mineral density (BMD) measured by dual x-ray absorptiometry (DXA) 8 weeks apart between treatment groups (baseline is when corticosteroids start and week 8 at completion of the steroids).

Key secondary outcome(s)

1. Do patients with ulcerative colitis and Crohn's disease have a differential response to steroid therapy or risedronate?
2. Change in markers of bone turnover (CTX for resorption and P1NP for formation) measured before steroids start (week -1), baseline and at week 8
3. Urinary steroid metabolites and cytokines measured from samples obtained at week -1

Completion date

30/09/2007

Eligibility**Key inclusion criteria**

1. Aged greater than or equal to 16 years, either sex
2. Ulcerative colitis and Crohn's disease
3. Experiencing a relapse
4. Requiring steroid therapy

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Aged under 16 years
2. Use of corticosteroids in the preceding 3 months
3. Evidence of osteoporosis (known vertebral fracture, T score less than -2.5)
4. Pregnant and lactating women
5. Women of childbearing age will be eligible provided they use reliable contraception
6. Bone active therapy within previous 12 months (excluding calcium and low dose vitamin D)
7. Previous treatment with a bisphosphonate at any time
8. Associated disorder which may influence bone metabolism
9. Lactose intolerance

Date of first enrolment

01/10/2005

Date of final enrolment

30/09/2007

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Academic Rheumatology

Bristol

United Kingdom

BS10 5NB

Sponsor information

Organisation

University Hospitals Bristol NHS Foundation Trust (UK)

ROR

<https://ror.org/04nm1cv11>

Funder(s)

Funder type

Industry

Funder Name

Procter and Gamble Pharmaceuticals (UK) - educational grant.

Funder Name

The funder had no input into the study design, recruitment or the analysis of the results.

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	results	01/03/2010		Yes	No