

A randomised double blind placebo controlled trial assessing the effect of once weekly risedronate on bone mineral density in adults with cystic fibrosis

Submission date

16/05/2005

Recruitment status

No longer recruiting

Registration date

08/07/2005

Overall study status

Completed

Last Edited

31/07/2012

Condition category

Nutritional, Metabolic, Endocrine

☐ Prospectively registered

☐ Protocol

☐ Statistical analysis plan

☒ Results

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Charles Haworth

Contact details

Cystic Fibrosis Unit
Papworth Hospital NHS Trust
Papworth Everard
United Kingdom
CB3 8RE

Additional identifiers

Protocol serial number

P00961

Study information

Scientific Title

Study objectives

To assess the efficacy, tolerability and safety of the bone-sparing treatment Risedronate, in adult Cystic Fibrosis patients with low bone mineral density

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised double blind placebo controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Cystic fibrosis

Interventions

Once weekly risedronate or placebo

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Risedronate

Primary outcome(s)

Bone mineral density Z score at the lumbar spine or femoral neck

Key secondary outcome(s))

Not provided at time of registration

Completion date

31/07/2008

Eligibility**Key inclusion criteria**

80 cystic fibrosis patients with low bone mineral density. $Z \leq -1.0$ at the spine or femoral neck

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Breast feeding
2. Pregnancy or desire to become pregnant within three years
3. Transplant listed patients or transplant recipients
4. Previous gastroscopy proven oesophageal abnormalities
5. Renal impairment (patients with an elevated serum creatinine at the screening visit will have a creatinine clearance performed - a level over 30 ml/min will enable participation)
6. Hypocalcaemia at the screening visit (using serum corrected calcium)
7. Previous prescription of bone active drugs (bisphosphonates, hormone replacement therapy [does not include the oral contraceptive pill], raloxifene, calcitriol, calcitonin, teriparatide)
8. Biochemical evidence of vitamin D deficiency at the screening visit (25-hydroxyvitamin D level <10 ng/ml and an elevated parathyroid hormone [PTH])
9. Long term oral corticosteroid use (defined as daily oral corticosteroid use for >6 weeks at the time of recruitment or the likelihood of requiring prolonged oral corticosteroid use at the time of recruitment)
10. Previous poor clinic attendance or previous poor adherence
11. Pre-terminal illness or other serious concomitant illness

Date of first enrolment

01/07/2005

Date of final enrolment

31/07/2008

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Cystic Fibrosis Unit

Papworth Everard

United Kingdom

CB3 8RE

Sponsor information

Organisation

Papworth Hospital NHS Trust (UK)

ROR

<https://ror.org/01qbebb31>

Funder(s)

Funder type

Industry

Funder Name

Proctor & Gamble Pharmaceuticals (UK)

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	01/12/2011		Yes	No