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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
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/07/2005

Completion date
31/07/2008

Eligibility

Key inclusion criteria
80 cystic fibrosis patients with low bone mineral density. Z ≤-1.0 at the spine or femoral neck

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
80

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
England

United Kingdom

Study participating centre
Cystic Fibrosis Unit
Papworth Everard
United Kingdom
CB3 8RE

Sponsor information

Organisation
Papworth Hospital NHS Trust (UK)

Sponsor details
Papworth Everard
Cambridge
England
United Kingdom
CB3 8RE

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01qbebb31

Funder(s)

Funder type
Industry

Funder Name
Proctor & Gamble Pharmaceuticals (UK)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2011		Yes	No