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Risedronate treatment for Children with severe Osteogenesis Imperfecta

Submission date	Recruitment status	[_] Prospectively registered
04/02/2002	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/02/2002	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
03/11/2011	Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
B0696

Study information

Scientific Title
Bisphosphonate administration in children with severe osteogenesis imperfecta: A prospective randomised double blind controlled study of risedronate

Acronym
RICO trial

Study objectives
Children aged between four and seventeen who have osteogenesis imperfecta, which is a form of osteoporosis which causes multiple fractures, deformity and stunted growth, are to be offered Risedronate in a clinical trial aimed at increasing bone density.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Sheffield Research Ethics Committee. Date of approval: 06/12/1999 (ref: SS 98/183)

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Osteogenesis imperfecta

Interventions
Patients will be randomised to either low (0.2 mg/kg/week), medium (1 mg/kg/week) or high (2 mg/kg/week) dose of the bisphosphonate risedronate. Treatment will continue for 3 years.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Bisphosphonate risedronate

Primary outcome measure
Added as of 10/04/2008:
Number of incident non-vertebral fractures in each group at 2 years.

Secondary outcome measures
Added as of 10/04/2008:
The following were assessed at 2 years:
1. Total body and lumbar spine bone area
2. Bone mineral content
3. Areal bone mineral density and volumetric bone mineral density

Overall study start date
31/07/2001

Completion date
31/12/2007

Eligibility

Key inclusion criteria
Inclusion criteria amended as of 15/04/2008:
1. Children with osteogenesis imperfecta
2. Aged between 3 and 17 ("Aged between 4 and 17" at ethics approval. We subsequently had an approved amendment to reduce the lower age limit to 3 years; this applied to only one child)
3. Both male and female

Inclusion criterion provided at time of registration:
Children with osteogenesis imperfecta

Participant type(s)
Patient

Age group
Child

Lower age limit
3 Years

Upper age limit
17 Years

Sex
Both

Target number of participants
Added as of 10/04/2008: Planned recruitment: 60; Actual recruitment: 53

Key exclusion criteria
Added as of 10/04/2008:
1. Have a history of cancer
2. Have untreated rickets within one year prior to enrollment
3. Evidence of clinically significant organic or psychiatric disease on history or physical examination which in the opinion of the investigator would prevent the patient from completing the study
4. Have markedly abnormal pretreatment laboratory findings, except if in the opinion of the investigator, it would not prevent the patient from completing the study
5. Have a history of using anabolic steroids/estrogens/androgens within one year of enrollment
6. Have a history of using any of the following medications within 6 month of starting study drug for more than one month: calcitonin, vitamin D supplements >1000 IU per day, and calcitriol >1.5 mg/week
7. Have a history of using any bisphosphonate (except for more than a single dose of risedronate) and/or fluoride (>10 mg per day). Have a documented history of an abnormal or allergic reaction to bisphosphonates
8. Pregnancy or sexually active subjects unwilling to take appropriate contraceptive measures
9. Any limb-lengthening procedure within 6 of enrollment
10. Participation in another clinical trial, involving active intervention within 30 days prior to enrollment
11. Serum creatinine >150 µmol/L

Date of first enrolment
31/07/2001

Date of final enrolment
31/12/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Institute of Child Health
Sheffield
United Kingdom
S10 2TH

Sponsor information

Organisation
Arthritis Research Campaign (ARC) (UK)

Sponsor details
Copeman House
St Mary's Court
St Mary's Gate
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Derbyshire
United Kingdom
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info@arc.org.uk

Sponsor type
Charity

Website
http://www.arc.org.uk

ROR
https://ror.org/02jkpm469

Funder(s)

Funder type
Charity

Funder Name
Arthritis Research Campaign (ARC) (UK)

Funder Name
Alliance for Better Bone Health (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	01/01/2010		Yes	No