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Steroid induced osteopaenia: prophylaxis and treatment in paediatric rheumatic diseases

Submission date	Recruitment status	[X] Prospectively registered
22/08/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
15/09/2005	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
24/05/2016	Musculoskeletal Diseases	[ ] Record updated in last year

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

15936

Study information

Scientific Title
Steroid induced osteopaenia: prophylaxis and treatment in paediatric rheumatic diseases

Study objectives
That the bisphosphonate Risedronate will significantly reduce steroid induced osteopaenia in children and adolescents

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Juvenile Idiopathic Arthritis (JIA), Juvenile Dermatomyositis (JDM), Juvenile Systemic Lupus Erythematosus (JSLE)

Interventions
Randomised to receive either one alpha hydroxycholecalciferol (one-alpha) Or risedronate

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
One alpha hydroxycholecalciferol, Risedronate

Primary outcome measure
An improvement of 0.5 SDS in bone mineral density (BMD) in the treated group compared to the control

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/01/2006

Completion date
30/06/2009

Eligibility

Key inclusion criteria
Children and adolescents with JIA, JSLE, JDM, commencing steroids or currently treated with steroids between the ages of 4 and 18 years

Participant type(s)
Patient

Age group
Child

Lower age limit
4 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
300 (150 in each arm)

Key exclusion criteria
1. Children who are commencing steroids but where the duration of steroid treatment is expected to be less than 3 months (i.e. short term) should not be recruited
2. Children receiving intermittent pulses of intravenous steroids
3. Co-morbid conditions known to be associated with osteopaenia: Cystic fibrosis, malabsorption, severe renal disease, severe asthma, cancer, osteogenesis imperfecta, inflammatory bowel disease
4. Have a history of using any bisphosphonate (except for more than a single dose of risedronate) and/or fluoride (>10 mg per day)
5. Have a history of cancer
6. Have untreated rickets within one year prior to enrolment
7. 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
8. Have markedly abnormal pretreatment laboratory findings, except if in the opinion of the investigator, it would not prevent the patient from completing the study
9. Have a history of using anabolic steroids/estrogens/androgens within one year of enrolment
10. Have a documented history of an abnormal or allergic reaction to bisphosphonates
11. Pregnancy or sexually active subjects unwilling to take appropriate contraceptive measures
12. Any limb-lengthening procedure within 6 months of enrolment
13. Participation in another clinical trial, involving active intervention within 30 days prior to enrolment
14. Creatinine clearance <100 ml/min

Date of first enrolment
01/01/2006

Date of final enrolment
30/06/2009

Locations

Countries of recruitment
Northern Ireland

United Kingdom

Study participating centre
Dept of Rheumatology
Belfast
United Kingdom
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Sponsor information

Organisation
Greenpark Healthcare Trust (UK)

Sponsor details
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Sponsor type

Hospital/treatment centre

ROR
https://ror.org/02tdmfk69

Funder(s)

Funder type
Charity

Funder Name
Arthritis Research Campaign (ARC) (UK) (ref:15936)

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