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Intervention project Osteogenesis Imperfecta (OI) type I and IV: home based training program to increase exercise capacity, muscle strength and aspects of quality of life in children with Osteogenesis Imperfecta

Submission date
20/12/2005

Registration date
20/12/2005

Last Edited
19/03/2008

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Musculoskeletal Diseases

[ ] 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
04/331-k (METC UMCU)

Study information

Scientific Title

Acronym
ETOI

Study objectives
Children with Osteogenesis Imperfecta type I and IV would benefit from a gradual training program. Increased exercise capacity and muscle strength could increase quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Multicentre, randomised, single-blinded, active controlled, parallel group 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
Osteogenesis Imperfecta

Interventions
Training program for 12 weeks (two times/week).

Intervention Type
Other

Phase

Not Specified

Primary outcome measure
Exercise capacity and muscle strength.

Secondary outcome measures
Health related quality of life.

Overall study start date
02/02/2005

Completion date
02/08/2005

Eligibility

Key inclusion criteria
1. Osteogenesis Imperfecta Type I and IV
2. Between 8 and 18 years of age
3. Ambulatory

Participant type(s)
Patient

Age group
Child

Lower age limit
8 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
36

Key exclusion criteria
1. Osteogenesis Imperfecta type II and III
2. Retardation
3. Non-walking

Date of first enrolment
02/02/2005

Date of final enrolment
02/08/2005

Locations

Countries of recruitment
Netherlands

Study participating centre
KB 02.056.0, 3508 AB
Utrecht
Netherlands
3584 EA

Sponsor information

Organisation
University Medical Centre Utrecht (UMCU) (Netherlands)

Sponsor details
PO Box 85500
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3508 GA

Sponsor type
University/education

Website
http://www.umcutrecht.nl/zorg/

ROR
https://ror.org/04pp8hn57

Funder(s)

Funder type
Charity

Funder Name
Johanna Child Fund (Johanna Kinderfonds) (The Netherlands)

Funder Name

Foundation for paediatric rehabilitation (Stichting Bio-Kinderrevalidatie) (The Netherlands)

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	01/01/2008		Yes	No