

Interventieproject Osteogenesis Imperfecta (OI) type I en IV.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27497

Source

Nationaal Trial Register

Brief title

ETOI

Health condition

Osteogenesis Imperfecta type I and IV.

Sponsors and support

Primary sponsor: M.van Brussel, MSc. PhDcan

KB 02.056.0

Lundlaan 6

3584 EA

P.O. box 85090

3508 AB Utrecht

Tel +32302504030

Fax +32302505333

m.vanbrussel@umcutrecht.nl

Source(s) of monetary or material Support: "Johannakinderfonds"(heijenoordseweg 3 6813 GG Arnhem) and "stichting bio-kinderrevalidatie"(Wekerromseweg 8 6816 VS Arnhem)

Intervention

Outcome measures

Primary outcome

Exercise capacity and muscle strength.

Secondary outcome

Health related quality of life.

Study description

Background summary

Aim of this study is to investigate if children with Osteogenesis Imperfecta between 8 and 18 years of age benefit from a graded exercise program with respect to exercise capacity, muscle strength, functional outcome and quality of life. thirty-eight children with OI type I and IV between 8 and 18 years of age will be randomly assigned in two groups (RCT). eighteen children will be treated with a graded exercise protocol, by trained paediatric physical therapists, whereas the control group will not be treated and serve as the control group.

Study objective

Children with Osteogenesis Imperfecta type I and IV would benefit from a gradual trainingsprogram; increased exercise capacity and muscle strength could increase quality of life.

Study design

N/A

Intervention

Training program for 12 weeks (2 times/ week).

Contacts

Public

University Medical Center Utrecht (UMCU), KB 02.056.0,
P.O. box 85090

R.H.H. Engelbert
Lundlaan 6

Utrecht 3508 AB
The Netherlands
+31 (0)30 2504030

Scientific

University Medical Center Utrecht (UMCU), KB 02.056.0,
P.O. box 85090
R.H.H. Engelbert
Lundlaan 6

Utrecht 3508 AB
The Netherlands
+31 (0)30 2504030

Eligibility criteria

Inclusion criteria

1. Osteogenesis Imperfecta Type I and IV;
2. between 8 and 18 years of age;
3. ambulantory.

Exclusion criteria

1. Osteogenesis Imperfecta type II and III;
2. retardation;
3. non-walking.

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	02-02-2005
Enrollment:	36
Type:	Actual

Ethics review

Positive opinion	
Date:	14-08-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL87
NTR-old	NTR118
Other	: 04/331-k (METC UMCU)
ISRCTN	ISRCTN28577651

Study results

Summary results

1. J Pediatr. 2008 Jan;152(1):111-6, 116.e1. Epub 2007 Oct 24.

2. Takken T, Terlingen HC, Helders PJ, Puijs H, Van der Ent CK, Engelbert RH. Cardiopulmonary fitness and muscle strength in patients with osteogenesis imperfecta type I. J Pediatr. 2004 Dec;145(6):813-8.
