

# Interventieproject Osteogenesis Imperfecta (OI) type I en IV.

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	-
<b>Study type</b>	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

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**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

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## 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. <br><br>
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.<br>