# Physical fitness levels of wheelchairbound children and adolescents with osteogenesis imperfecta: a feasibility and reliability study

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To investigate whether children with OI who use a wheelchair (for long distances) can reliably perform a valid shuttle ride test in order to assess the levels of health-related fitness in this group.

**Ethical review** Approved WMO **Status** Recruitment stopped

**Health condition type** Musculoskeletal and connective tissue disorders congenital

**Study type** Observational non invasive

### **Summary**

#### ID

NL-OMON39147

#### **Source**

**ToetsingOnline** 

#### **Brief title**

Fitness levels of wheelchair-bound children and adolescents with OI

### **Condition**

Musculoskeletal and connective tissue disorders congenital

#### Synonym

brittle bone disease, Osteogenesis imperfecta

### Research involving

Human

### **Sponsors and support**

**Primary sponsor:** Universitair Medisch Centrum Utrecht

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### Source(s) of monetary or material Support: Revalidatiefonds

#### Intervention

**Keyword:** Exercise testing, Feasibility and reliability, Osteogenesis imperfecta, Wheelchair-bound children/adolescents

### **Outcome measures**

### **Primary outcome**

Reliability (test re-test reliability/reproducibility) of the shuttle ride test

Validity of the shuttle ride test (attained peak heart rate and peak

Maximal oxygen consumption (VO2peak) attained during the shuttle ride test

(health-related fitness);

respiratory exchange ratio);

Rating of perceived exertion directly after the shuttle ride test.

### **Secondary outcome**

Muscle force (grip strength and one-stroke push test);

Fatigue (18-item PedsQL multidimensional fatigue scale);

Activities in daily life (wearing an accelerometer for one week).

# **Study description**

### **Background summary**

Children and adolescents with osteogenesis imperfecta (OI) have lost a considerable part of the functioning of their body and for most of them it is difficult to participate in physical activities or sport programs as a consequence of real or perceived limitations imposed by their condition. The condition itself often causes hypoactivity, which leads to a deconditioning effect, a reduction in the functional ability and further hypoactivity. These poor fitness-levels compared to healthy peers have been well-documented by

means of exercise tests in children and adolescents with OI who are able to walk independently. Moreover, exercise testing has been used as a primary outcome measure of therapy and exercise program in children with OI. However, for children and adolescents with OI who use wheelchairs the fitness levels are still unknown.

### Study objective

To investigate whether children with OI who use a wheelchair (for long distances) can reliably perform a valid shuttle ride test in order to assess the levels of health-related fitness in this group.

### Study design

Feasibility and reliability study (observational, non-invasive)

### Study burden and risks

The participants will be asked to perform a shuttle ride test including respiratory gas analysis until voluntary exhaustion on two occasions. In general, performing a maximal CPET is safe for children and adolescents, even for those with diagnoses placing them in a high-risk group. A study of Alpert et al. (1983) evaluated the frequency of significant complications of exercise testing in 1,730 children and found an overall incidence of complications of 1.79%. The authors concluded that exercise testing in children has low morbidity and mortality. Moreover, the study of van Brussel et al. (2008) reported no adverse health or safety effects in children and adolescents with OI (type I and IV) who are able to walk and completed a maximal CPET on a cycle ergometer. The risks for bone fractures during the shuttle ride test as well as during the assessment of muscle strength will not be increased because of the dynamic nature of the movement and the low peak power during dynamic exercise. Since the \*make\* method will be used during the grip strength measurements, the participants will determine the self-generated muscle force, reducing the risks for complications. The same holds true for the 1SPT. The demographic, anthropometric, and accelerometry measurements do not include risks either.

### **Contacts**

#### **Public**

Universitair Medisch Centrum Utrecht

Lundlaan 6 Utrecht 3584 AB NL

#### Scientific

Universitair Medisch Centrum Utrecht

Lundlaan 6 Utrecht 3584 AB NL

### **Trial sites**

### **Listed location countries**

**Netherlands** 

# **Eligibility criteria**

### Age

Adolescents (12-15 years) Adolescents (16-17 years) Adults (18-64 years) Children (2-11 years) Elderly (65 years and older)

### Inclusion criteria

Wheelchair-bound patients with OI:

- \* Boys and girls aged 8 to 25 years, will be enrolled;
- \* Diagnosis of OI and using a wheelchair (for long distances);
- \* Modified Bleck score \* Treated at the ORSK consulting-hour, UMC Utrecht or Isala Klinieken;
- \* Sufficiently healthy to participate.; Healthy peers:
- \* Age- and gender-matched healthy peers will be enrolled;
- \* Prepubescent, pubescent, and postpubescent children.

### **Exclusion criteria**

Wheelchair-bound patients with OI:

- \* A medical status that contraindicates exercise (e.g. cardiomyopathy);
- \* The use of medication affecting exercise capacity;
- \* Unable to cooperate with the testing procedures (e.g. insufficient understanding of the Dutch language).;Healthy peers:
- \* A medical status that contraindicates exercise;
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- \* The use of medication affecting exercise capacity;
- \* Cardiovascular or respiratory disease;
- \* Impaired motor development;
- \* Morbid obesity (body mass index (BMI) >35 kg/m2);
- \* Unable to cooperate with the testing procedures (e.g. insufficient understanding of the Dutch language).

# Study design

### **Design**

Study type: Observational non invasive

Intervention model: Other

Allocation: Non-randomized controlled trial

Masking: Open (masking not used)

Control: Active

Primary purpose: Treatment

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 13-08-2013

Enrollment: 30

Type: Actual

### **Ethics review**

Approved WMO

Date: 06-11-2012

Application type: First submission

Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO

Date: 10-12-2013
Application type: Amendment

Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

# **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

CCMO NL41053.041.12