Physical fitness levels of wheelchair-bound 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

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

respiratory exchange ratio);

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

(health-related fitness);

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

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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 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;

* 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