Norm values six-minute walktest for Dutch children.

Published: 26-11-2013
Last updated: 22-04-2024

Primary objective: To determine reference values for the 6-Minute Walk Test for Dutch healthy children, when the test is performed according to the ATS guidelines.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON47191

Source
ToetsingOnline

Brief title
6MWT Dutch children

Condition

- Other condition

Synonym
sub-maximal exercise tolerance

Health condition

Verzamelen normwaarden submaximale inspanningstest bij gezonde kinderen.

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: children, Dutch, Six-minute, walktest

Outcome measures

Primary outcome

Main study parameter/endpoint

The main study parameter /endpoint is the distance covered by the child when

walking on a flat hard surface for the duration of six minutes.

Secondary outcome

Secondary study parameters are:

Heart rate at onset of the test, heart rate on completion of the test, heart

rate at 2 and 5 minutes after completion of the 6MWT.

Other study parameters are:

Age, height, weight, oxygen saturation at onset and on completion of the 6MWT,

oxygen saturation at 2 and 5 minutes after completion of the 6MWT,

parent-questionnaire.

Study description

Background summary

The 6 minute walk test (6MWT) is a widely used test for measuring sub-maximal exercise capacity, i.e. the functional exercise capacity needed in everyday life.The 6 MWT measures the distance that the participant can quickly walk on a flat hard surface in a period of 6 minutes. The test is self-paced. The 6MWT was originally developed to measure the submaximal level of functional capacity in adult patients. The American Thoracic Society (ATS) has published guidelines for performing the 6 MWT with adults in a clinical setting. Nowadays the 6MWT is used regularly in pediatric populations as well, for example children with

mucopolysaccharidosis, Duchenne muscular dystrophy, spina bifida and children with malignancies. It is found to be a useful test for children who are moderately or severely impaired. A number of studies have produced reference values for children. Two of the studies involved a European cohort. In one of these the age span is too small. The other European study by Geiger et al investigated 528 healthy Austrian children. However, in this study the 6MWT was modified: to overcome lack of motivation children were provided with a measuring wheel with an instantaneous display of the walking distance. The reference values published by Geiger et al are therefore not applicable when the 6MWT is performed according to the ATS guidelines. In addition, living circumstances in Austria are different in terms of altiitude and also in the fact that a large part of the population does not live in urban areas.

Study objective

Primary objective:
To determine reference values for the 6-Minute Walk Test for Dutch healthy children, when the test is performed according to the ATS guidelines.

Study design

The study has a cross-sectional observational design.

Sample size:
The study aims to establish norm values for the 6MWT for the Dutch population. We propose additional testing of 20 boys and 20 girls aged 4 years en 20 boys and 20 girls aged 5 years resulting in 2 x 40 children. In comparison to the Geiger et al study the sample will be as below.
Male 4-5 years Geiger et al n=22; current study n=40
Female 4-5 years Geiger et al n=25; current study n=40

Investigated test:
The 6 minute walk test (6MWT) will be investigated. This test is designed to measure sub-maximal functional exercise capacity, i.e. the exercise capacity needed in everyday life. During the 6MWT children are requested to cover a distance of 20 meters (marked by 2 pylons) as often as possible, for a period of six minutes. Running is not permitted. The test is self-paced. Standardised verbal instruction and encouragement i.e. *you rare doing well, carry on* and *one minute has passed, another five minutes to go* as specified in the guidelines of the American Thoracic Society, will be used.

Consent:
Informed consent will be obtained from parents. Parents who give consent will be asked to fill out a short questionnaire regarding their child*s state of health and level of physical activity. This will take parents approximately

5-10 minutes.

Test procedure:
The test will be conducted at school, during school hours. Children will be requested to wear light clothes and shoes or trainers. Children will be instructed not to exercise 2 hours prior to the test. Parents will be requested to be present during the test procedure.The child will be collected during the PE classes by the parent. Weight will be measured with an electronic scale (Beurer PS-16 , Beurer, Ulm Germany). Height will be measured with a stadiometer (Seca 206, Seca , Hamburg, Germany). Heart rate and oxygen saturation will be measured with a finger pulse oximeter (Beijing Choice Electronic Technology Co. Ltd, Beijing, China), at the start and on completion of the test.This is not painful or uncomfortable.
The 6 MWT will be explained an demonstrated by the investigator. The child will then perform the 6MWT. During the test only standardised encouragements, as described in the ATS guidelines, are given. Each minute the child will be informed how many minutes have passed and how many minutes of the test remain. The number of times the complete distance between the pylons is covered is recorded. The additional distance past the last pylon is measured with a tape measure.

Duration:
The complete testing procedure will take approximately 15 minutes per child.

Recruitment:
In order to recruit healthy Dutch children primary schools reflecting those of the general popualtion will be contacted. The principals of the school will be approached with a letter, followed by personal contact. If the school is willing to participate, parents will receive a letter explaining the purpose and procedure of the study. They will be asked to make their decision know by filling out the consent form. The will be given 14 days to make their decision known. Parents who give their consent will receive a short questionnaire about their child*s state of health, his or her regular physical activities and amount of exercise.

Study burden and risks

Benefits and burden:
The 6 minute walk test (6MWT) is a useful tool as it measures sub-maximal functional exercise capacity, i.e. the exercise capacity needed in everyday life to participate in physical activities with peers. At present there are no norm values for Dutch children. Reference values from a pediatric Caucasian cohort from Austria are used in which the test procedure was modified. New norm values therefore need to be determined for the Dutch pediatric population.

The burden of the test is considered to be minimal. Measurement of heart rate and oxygen saturation takes place with a finger clip and is neither painful nor uncomfortable. The instructions of the test are easy to understand. The test is self-paced, therefore the child determines his or her own level of exertion. The duration of the task is short, i.e. 6 minutes. The complete test procedure takes 15 minutes and will take place during Physcial Eexercise classes during school hours, with one of their parents present. The activity requested for the test also takes place in everyday life. During the test the child is observed continually.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

In addition to the primary study involving children aged 6-18 we would like to include healthy Dutch children aged 4-5, with normal weight and height for age, attending regular education.

Exclusion criteria

- chronic disease or disability
- lower limb fracture or injury 1 year prior to the study
- using prescription medication
- unwell at the time of the study, i.e. running cold
- heart rate at rest when commencing the test not within norm values

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-11-2013
Enrollment:	340
Type:	Actual

Ethics review

Approved WMO Date:	26-11-2013
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-01-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam

	(Rotterdam)
Approved WMO Date:	19-06-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL44872.078.13