Anaerobic threshold in patients with pectus excavatum

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Observational non invasive

Summary

ID

NL-OMON42298

Source
ToetsingOnline

Brief title
Anaerobic threshold pectus excavatum

Condition

- Cardiac disorders, signs and symptoms NEC
- Thoracic disorders (excl lung and pleura)

Synonym
funnel chest, pectus excavatum

Research involving
Human

Sponsors and support

Primary sponsor: Atrium Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Anaerobic threshold, Exercise Testing, Pectus excavatum

Outcome measures

Primary outcome

- The anaerobic threshold is shown as percentage of the predicted VO2max.

Secondary outcome

- VO2max

- Heart ratemax

- Subjective exercise intolerance

- Cosmetic / psychological problems

- Borg scale (for both respiratory load as well as the fatigue in the legs)

- Short Form 36 questionnaire

Study description

Background summary

Pectus excavatum is a condition characterized by a dent in the chest wall, at the location of the 4th to the 7th rib, which usually has a funnel-like shape. Pectus excavatum can be calculated by using the Haller index. The Haller index is the thorax transversal distance divided by the distance between sternum and spine. The distances are assessed on an X-ray. Normal Haller index is <2.5, all values above 2.5 are called pectus excavatum. However, the degree of symptoms is not determined by the Haller index. Patients with a Haller index of 3.5 may have more symptoms than patients with an index of 5.5.
The shape of pectus excavatum is not always symmetrical. The deviation can be a severe deformity of the chest wall. The incidence is not fully known but it is expected that at least 1 in 1,000 born children has pectus excavatum. Usually boys are affected (85%) and pectus is more common in families with a member already familiar with pectus excavatum. If the deviation is seen at all after birth, then it is often not included in the medical record.
That heredity plays a role in the occurrence of pectus excavatum is known, but the exact mechanism not entirely clear. However, research shows that pectus

excavatum is more common in hereditary syndromes such as Ehlers danlos-, marfan- or poland syndrome.
Usually the cosmetic aspect of pectus excavatum plays an important role in a surgical intervention, however because of the reduced space in the chest pressure is exerted on the right atrium and the right ventricle of the heart. This can result in cardio compression.
The chest wall is very flexible when patients are young , therefore the heart is able to divert, so no complaints arise. However, as the patient gets older, the chest wall is less flexible and often creates a thoracic kyphosis by the collapse of the intervertebral discs, which gives even less deflection space. The resulting symptoms can also give a reason for surgical intervention.
These complaints are difficult to objectify. There are several markers that can give some information for this purpose, such as the aerobic capacity. The turning point from aerobic to anaerobic metabolism, also called "anaerobic threshold" (AT), could possibly give a good indication of physical problems. In multiple studies the subject of aerobic capacity after performing a Nuss procedure is discussed, but not the AT.

Study objective

The objective of this study is to demonstrate the influence of pectus excavatum on the anaerobic threshold during exercise. This could be an objective measurement of exercise intolerance. An objective measurement of exercise intolerance can later help in the decision for surgical treatment of pectus excavatum. Furthermore, the effect of a thorax correction on the AT can be examined.

Study design

The study design is a prospective design. Differences of the anaerobic threshold can be checked pre- en postoperatively and the measurement points can be chosen relatively freely.
Randomization can not be applied, because there is one group of patients with pre- and post-tests.
Informed consent will be obtained.
Patients have minimally five days to think about participating in this study. After this period, patients will be included.

Intervention

All patients, whom qualify for a Nuss procedure, are asked to participate in this study. These are patients between the ages of 18 and 40. During outpatient consultation patients receive information about the study, or will be contacted by phone at least one week before surgery. After the time for consideration patients will have to decide whether they want to participate or not. The pectus operations can not be performed immediately so the patients will have

more than five days to consider their participation. All patients will be planned for the Nuss procedure regardless of their choice to participate in the study. The preoperative investigations are completed and a bicycle test with determination of the AT is performed on the day of surgery.
The AT will be measured, in collaboration with the Department for pulmonology, before thoracic correction. Patients have to do a maximum effort bicycle test during which the AT can be seen. This test will be done a second time 3 months after the operation and a third time 1 year after the operation, so patients have had more time to recover.
Then all values will be compared. The AT is determined by means of the maximal oxygen uptake (VO2 max). The cut-off value for normal AT is > 40% of the predicted VO2 max.
All values of the test will be obtained non-invasively. The gold standard for the AT determination is described as drawing arterial blood and determining the actual lactate value at different times during the test. However, the AT can be accurately determined non-invasively (V-slope) in patients with cardiopulmonary disease. Because the non-invasive AT determination is similar to the gold standard and an invasive measurement would be an additional burden for the patient the V-slope method according to Wasserman, which is VO2 versus VCO2, is used. If the AT is above 40% of the predicted VO2max the AT then can be called normal.

Study burden and risks

It is known that the maximal oxygen uptake (VO2max) is lower in people with pectus excavatum before correction of the chest wall than in people without pectus excavatum. However, VO2max as a measurement of cardiopulmonary limitation in pectus patients can have drawbacks. If patients do not perform the maximum load during a bike test, VO2max may not always reflect the true clinical status of the patient and in such case AT can give more information than the VO2max.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Age between 18 to 40 years
- Planned for reconstruction of the chest wall with Nuss Procedure
- Haller index >2,5
- Symptoms related to exercise

Exclusion criteria

- Severe lung disease
- Preexisting heart disease
- Not able to do a cycle exercise test
Absolute contra-indications for exercise test:
- Acute myocardial infarction
- Unstable angina
- Syncope
- Active endocarditis
- Acute myocarditis
- Symptomatic severe aortic stenosis
- Uncontrolled heart failure
- Acute pulmonary embolus or infartction
- Thrombosis of lower extremities
- Suspected aortic dissection
- Uncontrolled astma
- Pulmonary edema
- Saturation in rest * 85%

- Respiratory failure
- Acute nonpulmonary disorder that may affect exercise performance
- Non-cooperative patient

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	27
Type:	Anticipated

Ethics review

Approved WMO

Date:	26-05-2015
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 28687
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL51528.096.15
Other	Registratiedatum NTR: 29-04-2015
OMON	NL-OMON28687