Anaerobic threshold in patients with funnel chest

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28687

Source
NTR

Health condition

Pectus excavatum
Funnel chest
Chest wall deformity
Anaerobic threshold
Exercise intolerance
Right ventricle compression

Sponsors and support

Primary sponsor: Atrium Medical Centre Heerlen
Source(s) of monetary or material Support: Atrium Medical Centre Heerlen

Intervention

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.

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 objective

- In patients with pectus excavatum the anaerobic threshold value is lower (<40% of predicted VO2max) than in people without pectus excavatum.

- After surgical correction of the thoracic wall the anaerobic threshold will rise above 40% of the predicted VO2max

Study design

- Preoperatively

- 3 months

- 1 year

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.

Contacts

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Eligibility criteria

Inclusion criteria

- Age between 18 and 40 years

- Scheduled for Nuss procedure

- Haller index >2,5

- Effort related complaints:

• Exercise intolerance

• chest pain

• poor stamina

• shortness of breath

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
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	04-05-2015

Enrollment:	27
Type:	Anticipated

Ethics review

Positive opinion
Date: 29-04-2015
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 42298
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5042
NTR-old	NTR5181
CCMO	NL51528.096.15
OMON	NL-OMON42298

Study results

Summary results
N/A