Abdominal Wall function following (Endoscopic) Component Separation Technique.

Published: 20-03-2018
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Primary Objective: Investigate if a release of the EOM in patients undergoing a VHR with retromuscular mesh gives (long term) loss of function of the AW .

Ethical review	Approved WMO
Status	Pending
Health condition type	Soft tissue therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON47520

Source
ToetsingOnline

Brief title
The *ABWA-study*

Condition

- Soft tissue therapeutic procedures

Synonym
Abdominal wall reconstruction.

Research involving
Human

Sponsors and support

Primary sponsor: Elkerliek ziekenhuis Helmond
Source(s) of monetary or material Support: eigen gelden

Intervention

Keyword: Abdominal wall, Biodex, Function, Strenght

Outcome measures

Primary outcome

Main study parameters/endpoints: Patients will be tested on several items related to the function of the EOM in the AW. These items are; Peak torque (Nm), peak torque per bodyweight of the abdominal wall, measured with the Biodex S4 pro. Backpain measured with the Quebec Back Pain Disability Scale and health related quality of life with the Carolina Comfort Scale.

Secondary outcome

n.v.t.

Study description

Background summary

Rationale: With an occurrence rate up to 29%, is an incisional hernia (IH) a common complication of abdominal surgery. An elective reconstructive surgery is necessary when the hernia causes pain, limitation of daily life function, complications and poor cosmetics.
One more often used technic for complex IH is the (endoscopic) components separation technique ((E)CTS). This technic is based on enlargement of the abdominal wall surface by separation and advancement of the muscular layers by releasing the external oblique muscle (EOM). Release of the EOM is likely to give a disadvantage on the function of the AW, as well in strength as in function. This is likely to give complains/constrains for the patient.
The aim of this study is to compare the function of the AW and the long term complains in patients how had and ventral hernia repair (VHR) with retromuscular mesh with or without release of the EOM.

Study objective

Primary Objective: Investigate if a release of the EOM in patients undergoing a

VHR with retromuscular mesh gives (long term) loss of function of the AW .

Study design

Study design: Observational study.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Patients will have one hour of tests without any risks.

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

The operated population:
- The operation was a ventral hernia repair with retromuscular mesh without release the external oblique muscle (EOM) or with bilaterally release of the EOM. (criteria only for the operated population)
- Operation is conducted more than 6 months ago.
The operated and healthy population:
- Able to for fill questionnaires
- Able to execute tests for the AW
- Living within 25 kilometre of the test location.

Exclusion criteria

The operated population:
- The operation is complicated
- Participant of the PHASIX-trail.
- Recurrence of the ventral hernia.
The operated and healthy population:
- Objective back problems (before operation)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	31-12-2017
Enrollment:	30

Type:	Anticipated

Ethics review

Approved WMO Date:	20-03-2018
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL61669.100.17