The Cardio Thoracic Harness

Published: 23-08-2006
Last updated: 10-08-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Thoracic disorders (excl lung and pleura)
Study type	Interventional

Summary

ID

NL-OMON29837

Source
ToetsingOnline

Brief title
The Cardio Thoracic harness

Condition

- Thoracic disorders (excl lung and pleura)
- Cardiac therapeutic procedures

Synonym
pain after heart surgery

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: harness, heart surgery, pain, thoracic

Outcome measures

Primary outcome

The primary study parameter is pain. Pain can be seen as the central factor. From the literature can be concluded that when a patient experiences a lot of pain a patient will be possibly mobilised not so fast and less frequent. Pain can also lead to fear related to pain. If a patient experience a lot of pain to the chest by activity he or she will possibly develope some fear for pain to activity. Pain can lead to a diminished lung function. When a patient experience a lot of pain to the chest by breathing deeply, he or she will breath less deeply. This results in a diminished lung function. The pain intensity will be measured with the National Rating Scale.

Secondary outcome

The secundary study parameters are:

- lung function: With the help of spirometry the patients lung volume and lung capacity can be measured. The lung function will be measured during three days ones a day.
- Mobility and independence: With the use of the Barthel Index score the extent of (in) dependence can be measured. The Barthel Index will be scored during three days ones a day.
- Fear related to pain: The Tampa Scale for Kinesiophobia will be used to measure fear related to pain. The score on this questioning can give information about the extent of possible fear related to pain during the days after the surgery. The questioning contains 17 questions.

Study description

Background summary

There is less reliable research to the effect of a new product, the Cardio Thoracic Harness. Earlier research has been done to a variant of the Cardio Thoracic Harness, The Sternum Support Harness. In this publicated research the writer concludes that the sternum Support harness may have a positive effect on pain management after open heart surgery but more research is needed to verify this. Also a larger patient population is necessary.
Another factor of relevance can be found in the literature. There is a growing interest in improving postoperative pain management. This increased interest can be concluded from the growing availability of effective methods for pain management and a growing awareness of effects of postoperative pain relief.
The central problem statement of this research is if the Cardio Thoracic Harness reduces pain after a sternotomy.

Study objective

The objective of this study is to get insight in the effect of the Cardio Thoracic Harness for men and the Cardio thoracic bra for women. The harness and the bra possibly have an important role in pain management. The producer of the harness and the bra describes that the harness and the bra can help stimulating the patient to cough effective and to breath deeply. The producer describes that the harness and the bra could lead to more comfort for the patient and more support of the chest. Together these aspects could lead to a fast recovery. Fast recovery leads to a fast discharge from the hospital. Fast discharge leads to a cost reduction.

Study design

It is an intervention study in which two groups will be compared. One group is the intervention group where the men get a harness and the women get a bra to wear. The control group receives the regular care, the use of a pillow. Between these two groups the same aspects will be measured. This makes it possible to compare the results of both groups. The aspects that will be measured are: pain intensity, lung function, mobility and independence and fear of pain.

Intervention

The intervention for men is the Cardio Thoracic Harness. For women they developed the cardio thoracic Bra. These products have to be worn 24 hours a day. This is necessary because also during the night support is needed by coughing, breathing deeply and mobilisation. The control group receives a

pillow.

Study burden and risks

The extent of the burden for the patients expressed in time is about 2 hours and 15 minutes. This time contains information about the research, instructions and the measurements. Except the lung function the data will be collected oral. The researcher will come to the patient twice a day to do the measurements.
The risks associated with participation to the research:
It could be possible that the Harness or the Bra not always offers comfort to the patients. This is because the products have to be worn continiously.

Contacts

Public
Universiteit Maastricht

P. Debeyeplein 1
6200 MD Maastricht
Nederland
Scientific
Universiteit Maastricht

P. Debeyeplein 1
6200 MD Maastricht
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- The need for open heart surgery
- The patient is between 65 and 79 years old

Exclusion criteria

- Insufficient knowledge about the Dutch language
- Cognitive deficit

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2006
Enrollment:	75
Type:	Actual

Medical products/devices used

Generic name:	The Cardio Thoracic Harness and the Cardio Thoracic Bra
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	23-08-2006
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL12175.068.06