

Chronic post-sternotomy pain, relation between accompanying painsymptoms and painlocation on the sternum

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The objective of this study is to prove that chronic post-sternotomy pain is not a local painproblem, but part of a general painsyndrom. Our hypothesis is twofold: 1. The investigated painsymptoms are of more frequently occurrence in the pain-sample...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Procedural related injuries and complications NEC
Study type	Observational non invasive

Summary

ID

NL-OMON29967

Source

ToetsingOnline

Brief title

Chronic post-sternotomy pain

Condition

- Procedural related injuries and complications NEC
- Cardiac therapeutic procedures

Synonym

chronic pain after open heartsurgery, post-CABG pain

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: chronic pain, sternotomy, thoraxsurgery

Outcome measures

Primary outcome

To have pain on the investigated locations.

Secondary outcome

not applicable.

Study description

Background summary

The incidence of chronic pain after sternotomy is about 30%. Chronic post-sternotomy pain is defined as pain lasting at least 3 months, arising after the surgery or being different from pre-surgery pain. There have been made several inquiries into this pain, but no unambiguous cause has been identified yet. Until now this pain has been looked at as a local problem, but with careful anamnesis and body examination, frequently other pain symptoms can be found, who have not been related to sternal pain before. This may imply that post-sternotomy pain is not a local problem, but part of a (typical) pain syndrome.

Study objective

The objective of this study is to prove that chronic post-sternotomy pain is not a local pain problem, but part of a general pain syndrome.

Our hypothesis is twofold:

1. The investigated pain symptoms are of more frequent occurrence in the pain-sample than in the pain-free sample.
2. The investigated pain symptoms can be matched as a pattern to the location of the pain on the sternum.

Study design

All patients that have undergone sternotomy in the period 2004-2005 in the LUMC will be sent an inquiry with pain questions. Those patients who want to

participate in the study, will be asked to come to the hospital once for a 30 minute body examination. Painsymptoms of the sternum, arms, shoulder, back, chest, neck and head will be investigated.

The patients are placed in 4 groups:

Group 1: patients with pain on the upper 1/3 part of the sternum

Group 2: patients with pain on the middel 1/3 part of the sternum

Group 3: patients with pain on the lower 1/3 part of the sternum

Group 4: patients with no pain on the sternum.

The frequency of the symptoms will be compared within the separated groups.

Study burden and risks

Almost no burden or risks are associated with participation. No invasive investigation will be done. Only one 30 minute visite to the hospital and 1 inquiry (6 minute) will be asked.

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

To undergo an open hartsurgery in the period between 1th january 2004 and 31th December 2005.

Exclusion criteria

Patients who died

Patient under 18 years

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	07-06-2006
Enrollment:	400
Type:	Actual

Ethics review

Approved WMO

Application type:

First submission

Review commission:

METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

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	NL12519.058.06