Sternum refixatie met behulp van ZipFix.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22106

Source
Nationaal Trial Register

Health condition

sternal closure , prevention of sternal complications after cardiac surgery, infection prevention and cardiac surgery

Sponsors and support

Primary sponsor: Catharina Ziekenhuis Eindhoven, the Netherlands
department of cardiothoracic surgery
Th.W.O.Elenbaas
Source(s) of monetary or material Support: no funding so far

Intervention

Outcome measures

Primary outcome

1. Dead within 30 days of operation;

2. Sternal wound infections (superfiscial, deep, organ-linked);

3. Sternal dehiscence.

Secondary outcome

Complants of sternal pain and sternal dehiscence after 1 year.

Study description

Background summary

Mediaan sternotomy is the approach in cardiac surgery and closure is done traditionally with steel wires , either in a single fashion or figure of eight configuration. One of the important outcome results is sternal dehiscence and or sternal infection. This is a complication with a high mortality and morbidity and around 20.000 euro extra coasts apart from the discomfort for the patients and worse outcome results.

The ZipFix sternal closure system is a new method for median sternotomy closure with tie - wrap like bands made of PEEK (poly ether ether ketone). The null hypotheses is that ther is no difference in complications as sternal dehiscence and or sternal infections. Patients will be prospectively randomised and followed for these complications for 1 year.

Study objective

Sternal closure is done routinely with stainless steel wires. In some cases thes wires are cutting through the bone and a non stable sternotomy can cause pain and lead to serious infections of the sternum and mediastinum. We hypothese that a new method for sternal closure is safer and better then the old standard method.

Study design

1. At discharge;

2. 6 weeks after OR;

3. 1 year after OR through telephone.

Intervention

Patients are randomized with the program Edgar II. Randomization is between:

1. Closure of the sternum with stainless steel wires;

2. Closure of the sternum with ZIPFIX bands, made of polyether ether ketone (PEEK).

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients undergoing median sternotomy;

2. Age above 18 year.

Exclusion criteria

1. No informed consent;

2. Hypersensitivity to nickel;

3. Allergic to PEEK.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2012
Enrollment:	600
Type:	Anticipated

Ethics review

Positive opinion

Date:	01-03-2012
Application type:	First submission

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
NTR-new	NL3204
NTR-old	NTR3355
Other	: SSZIPFIX
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A