Force-Controlled Retraction during Cardiac Surgery

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone and joint therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON30719

Source
ToetsingOnline

Brief title
Force-Controlled Retraction during Cardiac Surgery

Condition

- Bone and joint therapeutic procedures

Synonym
sternotomy, sternum retraction

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cardiac Surgery, Force-Controlled Retraction, Sternotomy

Outcome measures

Primary outcome

1)pain scale using the post-operative pain scale

2)use of analgetica

3)quality-of-life through a questionnair

Secondary outcome

1)heart rate

2)systolic blood pressure

Study description

Background summary

Cardio-thoracic surgery requires opening the thoracic skeletal cavity to provide adequate access and exposure. The most common approach is to gain access through the sternum along the anterior midline (the median sternotomy) and to harvest the internal mammary artery (lifting the sternum). Access to the cavity is achieved using mechanical retractors that exert significant forces on the skeletal cage. Currently, there is no data in the literature regarding the actual force and pressure generated during cardio-thoracic procedures. However, retraction is known to cause tissue damage that can result in acute and chronic pain post-operatively, as well as other co-morbidities.

Study objective

Our research objective is to test the hypothesis that patient outcomes can be improved through the development of instrumented retractors for cardiothoracic surgery. By monitoring and controlling retraction forces, damage to the chest wall and surrounding tissues can be minimized and post-operative pain can be reduced. When succesful this retractor can be made commercially available so it can be used widespread in order to minimize the burden on patients undergoing median sternotomy.

Study design

Randomized double-blinded single center clinical trial.
80 patients will be enrolled in this study, 40 control patients and 40 study patients. All patients will undergo a standard CABG-operation with the only difference that a modified retractor will be used that is equipped with a force-meter with which the forces used to open the thorax can be measured. in control patients these forces are recorded but not visible to the surgeon, while in study patients these forces are visible and the surgeon can reduce the forces used.
After operation patients fill in pain analog scales to keep track of the experienced pain. Another pain analog scale will be performed at the 2 week post-operative clinic and more pain analog scale and quality of life questionnaires will be performed by phone once every three month up one year. The usage of pain relief medication in hospitals and pain medication at home will be documented while performing the pain analog scale.

Intervention

Control group: 40 patients will undergo a median sternotomy according to the usual median sternotomy procedure. The LIMA will then be harvested using a modified LIMA-retractor. This retractor records the forces used to open the thorax.

Intervention group: 40 patienten will undergo a median setrnotomy. The LIMA will then be harvested using a modified LIMA-retractor. In this case the surgeon is able to observe the forces and influence these by open the thorax more gradually.

Study burden and risks

The potential risks are minimal. All cardiac and chest procedures will be conducted as they are with all other patients. We will use a commercially available retractor instrumented with strain gauges that perform precisely the same functions as conventional retractors, with the added information of the retraction force profile measurements. The main difference will be slower, force-controlled retraction, which may add 5 minutes to these procedures. However, since the total length of this cardiac procedure is usually 2-4 hours these extra minutes will account for a relatively small additional operation time.
The burden on the patients is mainly filling in a pain analog scale every day during their stay at the ward, which costs one minute a day. 2 weeks after surgery another pain analog scale will be taken and from then on once every three months. This will take 5 minutes a time.

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

1) Age above 18 without any limitation for maximum age
2) first-time CABG patients with the need for left internal thoracic artery (LIMA) harvesting through the median sternotomy

Exclusion criteria

Patients with history of chronic pain
Patients with previous median sternotomies.
Patients who use pain medication for other medical conditions

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-11-2007
Enrollment:	80
Type:	Actual

Medical products/devices used

Generic name:	Force controlled retractor
Registration:	No

Ethics review

Approved WMO

Date:	30-05-2007
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	NL15750.068.06