The "Spacemaker": evaluating a new surgical lung spatula for an optimal fit

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Cardiac arrhythmias
Study type	Interventional

Summary

ID

NL-OMON43471

Source
ToetsingOnline

Brief title
"Spacemaker"

Condition

- Cardiac arrhythmias
- Respiratory tract therapeutic procedures

Synonym
atrial fibrillation

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Stichting Technologische Wetenschappen (STW)

Intervention

Keyword: Cardiothoracic Surgery, Medical Device, Minimal Invasive Surgery

Outcome measures

Primary outcome

1) The feasibility to introduce a soft tissue expander trough a

mini-thoracotomy.

2) The feasibility to inflate and position the soft tissue expander in the

human hemithorax.

3) The feasibility to create a trans-soft tissue expander approach to the human

pericardium and to quantitatively assess the

working space on the pericardium.

Secondary outcome

* The hemodynamic response after implantation and optimal positioning of the

soft tissue expander.

o Change in heartrate

o Change in CVP

o Change in right ventricular pressure

o Change in PAP

o Change in CI

o Change in Arterial blood pressure

* The ventilatory response after implantation and optimal positioning of the

soft tissue expander while maintaining similar tidal volumes and ventilation

frequencies.

o Change in pulmonary airway pressure (maximum and mean)

o Change in carbondioxide end-tidal-pressure

o Change in lung compliance

* The respiratory response after implantation and optimal positioning of the soft tissue expander.

o Change in arterial blood oxygenation

o Change in arterial blood pCO2 and pO2

* Evaluating whether the optimal length size as obtained on CT-scan corresponds with the ideal length size in humans.

o The occurrence of possible complications due to tissue expander implantation.

o The occurrence of arrhytmias due to tissue expander implantation.

o The occurrence of atelectasis and the insufflation pressure necessary to re-expand the collapsed lung after removal of the soft tissue expander.

Study description

Background summary

Key requirements in surgery in general, are access to, exposure of and stability of the surgical target. Traditionally, cardiothoracic surgery is still highly invasive being associated with significant risks and discomfort. Although cardiologists offer decent minimal invasive alternatives to invasive coronary artery bypass grafting, the majority of patients undergoing percutaneous coronary intervention eventually have to undergo invasive bypass surgery in the long run. Even though there are several options available facilitating minimal invasive cardiac surgery, each option is associated with significant complications and hemodynamic and respiratory difficulties. In order to overcome these problems a new surgical platform has been advocated.

This platform should allow access, visualisation, exposure and presentation of the surgical target without interfering with organ function. Only whenever these requirements are met, minimal invasive cardiothoracic surgery can become reality.

Study objective

In our current study we would like to evaluate a newly developed surgical platform for minimal invasive cardiothoracic surgery: the soft tissue expander. Main objective of the study is to determine the feasibility of creating a trans tissue expander approach to the human pericardium and the mechanical stability during physiological two lung ventilation.
Secondary objective of this study are the evaluation of hemodynamic and respiratory response to device implantation, the occurrence of peri-operative complications and the occurrence of cardiac rhythm disorders due to device implantation.

Study design

prospective observational study without control group
During this study we will implant the soft-tissue-expander for a short periode of time during a thoracoscopische atrial fibrillation (AF) ablation. While doing this we will evaluate amongst others the ease of implantability, the geometrical fit and the hemodynamical and respiratory response once implanted.

Intervention

"Spacemaker" facilitated thoracoscopy

Study burden and risks

Individuals participating in this research are exposed to minimal adjuvant risks, apart from the risks involved in thoracoscopic atrial fibrillation ablation. The usage of the "Spacemaker" has been extensively studied in laboratory animals. These studies showed that the use of the "Spacemaker" in the chestcage is deemed safe and feasible. Furthermore, use of the "Spacemaker" was not associated with any significant damage to the lung tissue after 4 weeks of recovery.

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

* Age * 18 * 70 years
* Dutch speaking
* Patients undergoing thoracoscopic atrial fibrillation surgery
* Informed consent

Exclusion criteria

* Significant cardiac or respiratory comorbidity as assessed by cardiologist or anesthesiologist
* History of tuberculosis (TBC) or pleuritis
* Prior thoracic trauma
* Prior thoracic surgery
* Known allergy for poly urethanes of polyvinyl chloride

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	5
Type:	Anticipated

Medical products/devices used

Generic name:	The Spacemaker
Registration:	No

Ethics review

Approved WMO

Date:	06-07-2016
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	NL55718.068.15
Other	nummer aangevraagd - momenteel in behandeling bij trialregister.nl