Wound closure with OptiClose® System after median sternotomy - pilot study

Published: 28-11-2013
Last updated: 24-04-2024

Comparing the OptiClose® System with traditional skin wound closure with intracutaneous sutures on wound closing time, patient comfort, cosmetic results, surgical handling, and costs.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Tissue disorders NEC
Study type	Interventional

Summary

ID

NL-OMON39986

Source
ToetsingOnline

Brief title
COSMO trial - pilot

Condition

- Tissue disorders NEC
- Skin and subcutaneous tissue therapeutic procedures

Synonym
scar formation, Wound closure

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Median sternotomy, Wound closure, Wound foil with flip-over strips

Outcome measures

Primary outcome

Wound closure time.

Costeffectiveness

Secondary outcome

Patient comfort

Cosmetic results

Study description

Background summary

The OptiClose® System has been introduced recently in dermatological surgeries and showed a good cosmetic result, excellent wearing comfort for the patient and good handling characteristics for the surgeon. We would like to compare the characteristics (reduced operating time and increased patient comfort) of the OptiClose® System after median sternotomy.

Study objective

Comparing the OptiClose® System with traditional skin wound closure with intracutaneous sutures on wound closing time, patient comfort, cosmetic results, surgical handling, and costs.

Study design

Prospective randomized controlled pilot study

Intervention

In one group the skin wound after median sternotomy is closed by intracutaneous sutures and in the other group the skin is closed with the OptiClose® System.

Study burden and risks

There are no risks involved in participation in the study. Expected benefits for the patient are better cosmetic result of the scar and an increase of patient comfort during wearing the OptiClose® System.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 50
Rotterdam 3015 GE
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 50
Rotterdam 3015 GE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Adult patients (*18 year);
* Signed informed consent;
* Patients undergoing median sternotomy.

Exclusion criteria

* Current pregnancy;
* Allergy to any kind of wound foil;
* Previous median sternotomy;
* Future planned median sternotomy within 3 months;
* Poor comprehension of Dutch or absence of an interpreter

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-03-2014
Enrollment:	25
Type:	Actual

Medical products/devices used

Generic name:	OptiClose® System
Registration:	No

Ethics review

Approved WMO

Date:	28-11-2013
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	NL42487.058.13