Primary Closure of the lower limb and chest wound with Steri strip S in comparison with inter-cutane sutures in patients undergoing CABG.

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To investigate whether application of Steri-Strip* S will lead to: 1) shorter treating time 2) improved satisfaction with the patient 3) improved wound healing4) improved cost-efficiency5) improved satisfaction with the attendant

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

Summary

ID

NL-OMON32135

Source
ToetsingOnline

Brief title
Closure of the lower limb and chest woundwith Steri strip S.

Condition

- Procedural related injuries and complications NEC
- Skin and subcutaneous tissue therapeutic procedures

Synonym
cardiovascular disease, coronary artery disease

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: 3M Pharma Nederland B.V.,Maatschap cardiothoracale chirurgie financieren kosten van he onderzoek en de firma 3M financieren de steri-strip S pleisters.

Intervention

Keyword: closure, Coronary Artery Bypass, Esthetic, Surgery, surgical wounds

Outcome measures

Primary outcome

• Mean difference in treatment time

• Mean difference in satisfaction score in patients

• Mean difference in pain score

• Incidence of adverse events e.g. wound infection

• Mean difference satisfaction score of wound healing in experts

(cardiothoracic surgeon and dermatologist)

Secondary outcome

• Mean difference in costs-efficiency

• Mean difference in satisfaction score in attendants

• Use of pain medication after surgery

Study description

Background summary

During bypass surgery (CABG) usually a incision is made in thorax and a vein is harvested from the lower limb to use as a graft. The vein is surgically removed, thereby inflicting a wound in the lower limb from the ankle to the knee. These wounds are traditionally closed in two layers; one running subcutaneous suture and the skin is closed with a running intercutaneous

suture. Disadvantages of using a intercutaneous suture for closing of the skin are; (1) inflicting of micro traumata of the skin, by use of a needle, (2) intervariability between surgeons, (3) strangulation of the skin through a too tightly suture or dehiscence of the skin when a suture is too loose, (4) it is time consuming and (5) there are risk of needle stick injuries.
Now a days there alternative methods of closing the skin were these disadvantages are not present. These methods use adhesive strips which are placed on either side of wound-edges and subsequently are pulled together, after which they are fixated. These adhesive strips are commercially available with the firm 3M and called *Steri-Strip* S*.
Both methods are commonly used in the cardiothoracic surgery and general surgery. However both methods are never been compared to each other.

Study objective

To investigate whether application of Steri-Strip* S will lead to:
1) shorter treating time
2) improved satisfaction with the patient
3) improved wound healing
4) improved cost-efficiency
5) improved satisfaction with the attendant

Study design

A open, prospective, randomized mono-center study.

Intervention

Patients who are participating in this study are randomized in two groups. In both groups The wounds wil be closed with a running subcutanous suture. In one group the skin wil be closed with a monocryl running suture. In the other group the wound wil be closed using Steri-Strip* S. These strips are placed on either side of wound-edges and subsequently are pulled together, after which they are fixated. This causes the wound-edges to lay side by side. The strips wil remain attached to the patient for 14 days, after which they are removed.

Study burden and risks

Theoretically there is risk of adverse effect of the skin e.g. rash and dehiscence of the adhesive strip. Never the less these adverse effect are never been reported even though the Steri-Strip* S is widely used. Moreover is the Steri-Strip* S latex free.
possible benefits; Reduction of treating time, reduction of risk for surgical wound infection, improved wound healing, reduced pain sensation at surgical sites and lower costs.

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

patient undergoing coronary artery bypass surgery with patent superficial saphenous vein

Exclusion criteria

no

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2008
Enrollment:	80
Type:	Actual

Medical products/devices used

Generic name:	Steri Strip S
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	08-01-2008
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL20596.060.07