Closure after small skin incisions and excisions with a new closing system

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compare the SoClose system with traditional skin wound closure with intracutaneous suturs of small skin excision on: cosmetics, wound healing, closing time, patient comfort and costs.

Ethical review	Approved WMO
Status	Pending
Health condition type	Skin and subcutaneous tissue therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON43042

Source
ToetsingOnline

Brief title
CLASSICS trial

Condition

- Skin and subcutaneous tissue therapeutic procedures

Synonym
operation of the skin, skin excision

Research involving
Human

Sponsors and support

Primary sponsor: Maasstadziekenhuis
Source(s) of monetary or material Support: Close-it B.V.

Intervention

Keyword: dermatology, excision, skin, sutures

Outcome measures

Primary outcome

cosmetic result

Secondary outcome

patient comfort, surgical handling, wound infection, wound dehiscence, allergic

reaction, wound closing time and costs

Study description

Background summary

The SoClos system has recently been introduced in de dermatological surgery and already showed promising cosmetic results, excellent comfort for the patient during wearing and good handling characteristics for the dermatologist of surgeon. The SoClose system consists of a adhesive sheets and a flip-over system, which makes closing skin wounds accurate, simple and tension free. Before surgery, the wound is covered with an incision foil, through which the excision is made. At the end of the procedure the incision foil is removed and the skin is closed with the flip-over strips that are situated under the incision foil. We would like to compare the outcomes of woundhealing after excisions of small skin lesions with conventional woundclosing, the intracutaneous suturing with Monosyn.

Study objective

compare the SoClose system with traditional skin wound closure with intracutaneous suturs of small skin excision on: cosmetics, wound healing, closing time, patient comfort and costs.

Study design

A prospective multicenter cohort study

Intervention

wound closure with the SoClose system (woundfoil) instead of the conventional intracutaneous sutures.

Study burden and risks

There are no or minimal risks involved in participation in the study. A previous cohort study already showed that the SoClose system is a reliable and feasible system for closing small surgical wounds and showed promising results according to wound healing and cosmetics. Expected benefits for the patient are better comfort during wearing of the SoClose system, improved wound healing en better cosmetic result.
The burden of the study for the patient will include a visit the the outpatient clinic at 14 days and 6 months after excision and fill out questionnaires a those time points. Most patients not included in this study, also have a protocol visit to the outpatient clinic after 14 days when sutures have to be removes, or in follow-up after 6 months in case of a skin malignancy. Therefore, the extra burden of participating in the study is low.

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

adults, signed informed consent, skin lesion on the trunk or extremities, excision leading to a scar with margins <7.5 cm

Exclusion criteria

pregnancy, allergy to any kind of wound foil, poor comprehension of dutch language or absence of an interpreter, Moh's surgery

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2016
Enrollment:	200
Type:	Anticipated

Medical products/devices used

Generic name:	SoClose system
Registration:	No

Ethics review

Approved WMO Date:	20-07-2016
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	NL57665.101.16