Silicone gel sheet to improve cosmetic outcome of the scar after removal of an implantable central venous access device (ICVAD) in childhood cancer survivors.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Epidermal and dermal conditions
Study type	Interventional

Summary

ID

NL-OMON30005

Source
ToetsingOnline

Brief title
LiLa

Condition

- Epidermal and dermal conditions

Synonym
abnormal scarring, Hypertrophic scarring

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: central venous access., childhood cancer survivors, Hypertrophic scars, Silicone gel sheet

Outcome measures

Primary outcome

Outcome variables regarding scar aspect:

- Width in millimetres

- Length in millimetres

- Height (normal, 1-2 mm, 3-4 mm, 5-6 mm, >6 mm)

- Vascularity (normal, pink, red, purple)

- Pigmentation (normal, hypopigmentation, mixed pigmentation,

hyperpigmentation)

- Pliability (normal, supple, yielding, firm, adherent)

- Pain (nine point scale)

- Itching (nine point scale).

Children whose age is of twelve to eighteen years get standardized

questionnaires on body image (minimum score 8, maximum score 40) and quality of

life (functional and symptom status: 11 items with a range from 1-4, global

health status: 2 items with a range from 1-7).

Secondary outcome

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Study description

Background summary

Background.
Childhood cancer survivors often have physical scars with emotional consequences. Disfiguring scars can induce lower self-esteem or self-image. Therefore it is important for the child to improve the appearance of a scar. Causes of scars due to cancer, or its treatment can be diverse. Surgery on solid tumors, and bone marrow or lumbar punctures, catheters or central venous access devices can cause scars.
An implantable central venous access device (ICVAD) is located subcutaneously, preferable on the chest wall, and sometimes at the lower ribcage or in the antecubital area. Its application is common practice in children treated with chemotherapy. For unknown reasons disfiguring and extremely wide scars are observed after ICVAD removal. To determine the extent of abnormal scarring we studied the ICVAD scars of 50 childhood cancer survivors, treated at the VU university medical center. Both physical and psychosocial impact of the scar was evaluated. Abnormal scarring was evident. Both parents and children reported emotional distress by this scar. Based on these findings this intervention study is initiated.

Study objective

Aim.
The general aim of the study is to determine if cosmetic outcome will improve by applying silicone bandages to the wound. Cosmetic outcome is analyzed by size, colour, and surface of the scar. In addition it will be evaluated whether the therapeutic effect is influenced by the duration of silicone application.
The last aim of this study is to study whether there is a relation between cosmetic outcome after removal of an ICVAD, and psychosocial consequences of the scar.

Study design

Study design
The study is a prospective randomized multicenter trial with a pretest-posttest control group design, and will be performed at the Pediatric Surgical Center Amsterdam, located at the VU university medical center and the Emma Children*s Hospital, AMC (EKZ), Amsterdam.
The study includes two experimental groups and one control group.
Group A Patients in group A will receive a silicone gel sheet for two months (8 weeks).
Group B Patients in group B will receive a silicone gel sheet for six months (28 weeks).

Group C Patients in group C do not get a silicone gel sheet.
The study will be continued until 36 evaluable patients are included.

Intervention

Intervention.
The application of a silicone gel sheet to optimize wound healing after removal of the ICVAD, and to reduce the size of the scar.

Study burden and risks

Out of the children who participate in the study, two-third receive a silicone gel sheet. The duration of application differs from 8 weeks in the first group to 28 weeks in the other intervention group. During these weeks the silicone gel sheet is used for about 20 to 24 hours per day. There is a control group which does not get an intervention.
The silicone gel sheet presumably results in better scar outcome. A burden of being in the intervention group can be the discomfort by using and removing the silicone gel sheet from the skin. Sometimes rash is seen as a site effect of the silicone gel sheet use. But personal hygiene may minimize the change for getting rash.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Children between one and 18 years old, who are in follow-up for cancer treatment, and have an implanted central venous access device (ICVAD), which is planned to be removed.

Exclusion criteria

1. The implanted central venous access device (ICVAD) is located on an other location than the chest wall.
2. The ICVAD will be removed because of an infection.
3. The child received radiotherapy on the chest.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2006
Enrollment:	36
Type:	Anticipated

Medical products/devices used

Generic name:	Silicone gel sheet
Registration:	Yes - CE intended use

Ethics review

Approved WMO	
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL13175.029.06