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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20907

Source
NTR

Brief title
LiLa

Health condition

In childhood cancer survivors, for unknown reasons, disfiguring and extremely wide scars are observed after Implantable central venous access device (ICVAD) removal.

Sponsors and support

Primary sponsor: -
Source(s) of monetary or material Support: -

Intervention

Outcome measures

Primary outcome

Outcome variables regarding scar aspect:
1. Width in millimeters;
2. Length in millimeters;
3. Height (normal, 1-2 mm, 3-4 mm, 5-6 mm, >6 mm);
4. Vascularisaty (normal, pink, red, purple);
5. Pigmentation (normal, hypopigmentation, mixed pigmentation, hyperpigmentation);
6. Pliability (normal, supple, yielding, firm, adherent);
7. Pain (nine point scale);
8. 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

N/A

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.

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 the score on the quality of life and the body image scale.

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.

PATIENTS AND METHODS. This study is a prospective randomized multi center trial, with a pretest-posttest control group design. A total of 36 children will be included in the study. Inclusion in the study is possible when the child is between one and eighteen years old, is at the end of cancer treatment, and needs to have a surgical removal of the ICVAD. Exclusion criteria are previous radiotherapy on the chest wall, an ICVAD infection before removal, or an ICVAD located in an other area than the chest wall. Participants will be randomly assigned to one of the three study groups. Two groups will receive silicone gel sheets, for respectively two and six months, while in the third group (control group) participants will not get a gel sheet after surgery. Because of specific wound healing in children with a pigmented skin, these children are separately randomized, and analyzed by stratification. The duration of follow-up is one year post surgery for ICVAD removal. The study will be continued until 36 evaluable patients are included.

SCIENTIFIC AND SOCIAL RELEVANCE. Studies assessing the use of silicone gel sheets to prevent hypertrophic scarring are few, of poor quality, and are performed in populations other than childhood cancer survivors. This intervention study will provide information about the effect of silicone gel sheet application on hypertrophic ICVAD scars in childhood cancer survivors. In addition, application of silicone gel sheets may possibly increase quality of life as a result of reduced scarring. With a good scar outcome, there is no need for plastic surgery. Thereby it finally may also lead to financial benefits for childhood cancer survivors.

Study objective

1. ICVAD removal, followed by six months of silicone gel sheet use, will result in a scar width within the normal range, and normal scar structure, and thus will be superior to two months of silicone gel sheets and no gel sheets;
2. A smaller and/ or less hypertrophic scar will reduce the chance of being reminded to the stressful period during cancer treatment, resulting in a better body image and quality of life scores.

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.

Contacts

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Eligibility criteria

Inclusion criteria

1. Children who are in follow-up for cancer treatment, and have an ICVAD, which is planned to be removed, are eligible for the study;
2. The children should be between one and eighteen years old.

Exclusion criteria

Children are excluded for the study when they had an ICVAD on an other location than the chest wall, when the ICVAD was removed because of an infection, or when the child received radiotherapy on the chest. This latter criterion is because of the damage to the skin during radiotherapy.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-04-2007
Enrollment:	36
Type:	Anticipated

Ethics review

Positive opinion

Date:	24-10-2006
Application type:	First submission

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
NTR-new	NL802
NTR-old	NTR815
Other	: 06/146
ISRCTN	ISRCTN77132184

Study results

Summary results

A manuscript titled Hypertrophic scars due to implantable central venous access device in childhood cancer survivors (ASO-2006-08-0435) has been submitted by Dr. Antoinette Schouten-van Meeteren to the Annals of Surgical Oncology.