

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

Submission date 28/12/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 28/12/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 05/11/2008	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr H A Heij

Contact details

Academic Medical Centre (AMC)
Emma Children's Hospital and Vrije University Medical Centre
Department of Pediatric Surgery (9d32)
P.O. Box 22660
Amsterdam
Netherlands
1100 DD
+31 (0)20 566 5693
h.a.heij@amc.uva.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

06/146; NTR815

Study information

Scientific Title

Acronym

LiLa

Study objectives

1. Implantable central venous access device (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.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from the local medical ethics committee

Study design

Randomised, controlled, parallel group, multicentre trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Hypertrophic scarring

Interventions

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

Intervention Type

Device

Phase

Not Specified

Primary outcome measure

Outcome variables regarding scar aspect:

1. Width in millimetres
2. Length in millimetres
3. Height (normal, 1 - 2 mm, 3 - 4 mm, 5 - 6 mm, more than 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 standardised questionnaires on body image (minimum score eight, maximum score 40), and quality of life (functional and symptom status: 11 items with a range from one to four, global health status: two items with a range from one to seven).

Secondary outcome measures

No secondary outcome measures

Overall study start date

01/10/2006

Completion date

01/10/2008

Eligibility**Key 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

Participant type(s)

Patient

Age group

Child

Lower age limit

1 Years

Upper age limit

18 Years

Sex

Both

Target number of participants

36

Key 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.

Date of first enrolment

01/10/2006

Date of final enrolment

01/10/2008

Locations**Countries of recruitment**

Netherlands

Study participating centre

Academic Medical Centre (AMC)

Amsterdam

Netherlands

1100 DD

Sponsor information**Organisation**

Vrije University Medical Centre (VUMC) (The Netherlands)

Sponsor details

Van der Boechorststraat 7

Amsterdam

Netherlands

1081 BT

Sponsor type

Hospital/treatment centre

Website

<http://www.vumc.nl/>

ROR

<https://ror.org/00q6h8f30>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Vrije University Medical Centre (VUMC) (The Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration