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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	[_] Prospectively registered [_] Protocol
Registration date 28/12/2006	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 05/11/2008	**Condition category** Signs and Symptoms	[_] Individual participant data [_] 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