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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

Registration date
28/12/2006

Overall study status
Completed

Last Edited
05/11/2008

Condition category
Signs and Symptoms

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised, controlled, parallel group, multicentre trial

Study type(s)
Treatment

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(s)
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).

Key secondary outcome(s)
No secondary outcome measures

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
1 Years

Upper age limit
18 Years

Sex
All

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)

ROR
https://ror.org/00q6h8f30

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Vrije University Medical Centre (VUMC) (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration