Pressure and Silicone treatment in Hypertrophic Scarring

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The objective of our observational clinical trial is to quantify the apoptosisrates of fibroblasts and growth-factorchanges in hypertrophic (burn) scars treated with pressure and/or silicone therapy.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Injuries by physical agents
Study type	Observational invasive

Summary

ID

NL-OMON30255

Source
ToetsingOnline

Brief title
Hypertrophic Scarring

Condition

- Injuries by physical agents
- Epidermal and dermal conditions

Synonym
burn scars, Hypertrophic scarring

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Ziekenhuis Maastricht
Source(s) of monetary or material Support: Nederlandse Brandwonden Stichting

Intervention

Keyword: Hypertrophy, Pressure therapy, Scar, Silicones

Outcome measures

Primary outcome

Apoptosisrate of fibroblasts

Secondary outcome

Concentrations of TGFbeta 1, 2 and 3 and MMP 9

The histological findings will also be correlated to the clinical differences

in erythema and thickness.

Study description

Background summary

Hypertrophic scarring is a tremendous problem in (reconstructive) surgery and in particular in burncare. The excess scar formation leads to functional problems due to contractures, continuous pain and itching sensations and often to psychosocial problems.

Two of the most widely used treatments in hypertrohic scarring are pressure therapy and the newer silicone-therapy. Both treatmentmodalities work through applying continued pressure or occlusion, delivered by garnments or sheets which must be worn up to one year.

Although pressure and silicone therapy become more widely used, little is known about the histological workingmechanism of both.

Study objective

The objective of our observational clinical trial is to quantify the apoptosisrates of fibroblasts and growth-factorchanges in hypertrophic (burn) scars treated with pressure and/or silicone therapy.

Study design

In our study we will follow 120 patients with hypertrophic scarring. The studypopulation will consist of four patientgroups: one group with both pressure and silicones, one group with only pressure, one group with only silicones and one control group. At start, 1, 2, 3, 6, 12 and 18 months they will be evaluated by Colorimetry and Dermascan Ultrasound. Along with this clinical evaluation a 4 mm punch-biopsy will be taken.

In those scar samples apoptosis, necrosis and proliferation of fibroblasts and the concentrations of the most important growth-factors in wound maturation, TGF beta 1, 2 and 3 will be determined with immunoassay techniques, as also the concentration of the main remodeling proteinase, matrix metallo proteinase MMP9.

Intervention

The intervention consist of the application of pressure with or without silicone inlays on the hypertrophic scars.

Study burden and risks

Because of the non-invasive character of both pressure and siliconetherapy, no risk are forseen for patients participating in this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Only patients with an objectified developing hypertrophy as measured by colorimetry will be included. An erythema value of 140% of normal healthy skin is required.
- All scars younger than 6 months post-woundclosure can be included

Exclusion criteria

- Age <18yrs, > 65yrs
- Preëxistent skin disease
-Degenerative or metabolic disorders (use of immunosupressives, immuno

Study design

Design

Study phase:	3
Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2007
Enrollment:	80
Type:	Actual

Medical products/devices used

Generic name:	Pressure garments;silicone inlays
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	09-11-2006
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL14068.068.06