Application of a dermal substitute and topical negative pressure to improve the healing of burn wounds

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Ethical review	-
Status	Recruitment stopped
Health condition type	Epidermal and dermal conditions
Study type	Interventional

Summary

ID

NL-OMON30864

Source
ToetsingOnline

Brief title
VAC-M

Condition

- Epidermal and dermal conditions

Synonym
deep burns, full thickness burns

Research involving
Human

Sponsors and support

Primary sponsor: Rode Kruis Ziekenhuis
Source(s) of monetary or material Support: de Nederlandse Brandwonden Stichting

Intervention

Keyword: Burns, Dermal substitution, Topical Negative Pressure, Vacuum Assisted Closure

Outcome measures

Primary outcome

Primary end point: skin elasticity parameters (representing scar quality) after

3 months

Secondary outcome

Secondary end points: take of graft after 5-7 days, scar assessment scale and

scar colour/ pigmentation (Dermaspectrometer) after 3 months

Study description

Background summary

Background
The standard therapy for full thickness wounds is transplantation with a split thickness skin graft. However, scars usually develop as a result of this therapy.
Previous research has demonstrated an improvement of scar quality if a dermal substitute was applied in combination with a split skin graft in reconstructive wounds, but not so much in burn wounds. One of the problems in burn wounds was the retarded outgrowth of the skin graft when a dermal substitute was applied in a one step procedure with the graft. Since then, application of topical negative pressure has demonstrated that the take and outgrowth of a skin graft can be improved by this technique. It now seems feasible to combine these two technologies in order to try and improve the quality of healing of burn wounds in the acute phase of healing.

Study objective

Aim of the study is to investigate if application of a dermal substitute in combination with topical negative pressure can improve the quality of the scar in burn wounds.

Study design

This study is designed as a four-armed prospective comparative study, to be conducted in the three dutch burn centers, comparing split skin graft with and without topical negative pressure (TNP) and the dermal substitute Matriderm and split skin graft with and without TNP in adult patients with acute full thickness wounds.

Intervention

Group 1: the selected wound will be treated with dermal substitute Matriderm, split skin graft and VAC therapy
Group 2: the selected wound will be treated with dermal substitute Matriderm, and split skin graft
Group 3: the selected wound will be treated with a split skin graft and VAC therapy
Group 4: the selected wound will be treated with a split skin graft.

Study burden and risks

The burden for the patients participating in this study is minimal: the experimental components of the treatment are added to the usual treatment for deep wounds that these patients will receive anyhow. Extra burden is represented by the fact that patients in two out of four groups will receive Vac therapy. This therapy may limit their freedom of motion during 3 to 5 days to some extent. Patients entering this study will be evaluated somewhat more extensively during outpatient follow up visits, at 3 months post-operatively. This will take approximately 30 to 60 min of their time in total.
Risks associated with the study are a possibly retarded outgrowth of the split skin, especially in group 2. The chances that the skin graft is lost are judged to be minimal, based on a previous study (Van Zuijlen et al, Plast. Rec. Surg. 2000; 106, 615-623).

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

Inclusion criteria:-patients => 18 yrs with acute burns/trauma wounds that require skin grafting
-Minimal study wound surface 10 cm2
-Maximal study wound surface 300 cm2
-maximal TBSA 15% full thickness wounds
-Informed consent

Exclusion criteria

Exclusion criteria:
-Patients with wounds without adequate possibility to apply VAC
-Immunocompromised patients
-Infected wounds
-Pregnant patients
-Patients who are expected (according to the responsible medical doctor) to be non-compliant to the study protocol. This includes patients with severe cognitive dysfunction/impairment and severe psychiatric disorders (e.g. borderline or depression).

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2007
Enrollment:	72
Type:	Anticipated

Medical products/devices used

Generic name:	Matriderm Collagen-Elastin Matrix for dermal regeneration
Registration:	Yes - CE intended use

Ethics review

Not available

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	NL18500.094.07