Scar quality in Burn Wounds with Various Healing Potentials:A Pilot Study

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To determine long-term scar quality in patients admitted to a Dutch burn centre with burn wound of indeterminate depth.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Injuries NEC
Study type	Observational non invasive

Summary

ID

NL-OMON41119

Source
ToetsingOnline

Brief title
Scar quality after burns

Condition

- Injuries NEC
- Skin and subcutaneous tissue disorders NEC

Synonym
burn injuries, thermal injuries

Research involving
Human

Sponsors and support

Primary sponsor: Vereniging Samenwerkende Brandwondencentra Nederland
Source(s) of monetary or material Support: eigen geld VSBN

Intervention

Keyword: burns, scar quality, time to wound healing

Outcome measures

Primary outcome

Self-reported scar quality using the Patients Observer Scar Assessment Scale

(POSAS).

Secondary outcome

Scar elasticity with the Cutometer® Skin Elasticity Meter 575

Vascularity and pigmentation with the Dermaspectometer

Study description

Background summary

Nowadays, scar formation and quality are considered as one of the most important outcomes in burn wounds. It is generally accepted that superficial dermal burns with an expected wound healing of less than 14 days require no surgical intervention, and that deep dermal or subdermal (full thickness) burns with a healing potential of more than 21 days require surgical intervention. In full-thickness and deep partial-thickness burns there will be scarring regardless of intervention, however early excision and grafting is shown to be positively correlated with scar quality.
However, clinical decision-making in burns of indeterminate depth, with a healing potential within 14-21 days, is less straight forward. In addition, often the depth of a burn is not either superficial dermal or deep dermal but a mix of depths. In these cases, early excision and grafting could be overzealously and cause scarring in areas that would have been able to reepithelialise without surgical intervention. Conservative treatment could give the superficial dermal areas time to reepithelialise with little or no scarring, but postponing excision of the deep dermal areas too long will cause more extensive (hypertrophic) scars. Hence, clinical decision-making is unclear and evidence is missing regarding wounds with an intermediate healing potential (14 to 21 days) and mixed wounds.

Study objective

To determine long-term scar quality in patients admitted to a Dutch burn centre with burn wound of indeterminate depth.

Study design

In a prospective cohort study we will determine scar quality > 15 months post-burn in all patients included in a previous trial conducted at our burn centre(s). For this trial (NL37844) patients burn wounds have been carefully documented and depth has been determined with LDI scans. Hence, using these data, a high quality study can be conducted with minimal efforts.

Intervention

Not applicable

Study burden and risks

Burden for patients will be minimal. As the assessment of scar outcome by Patient and Observer Scar Scale, Cutometer®, Dermaspectometer® are all non-invasive measurements requiring limited registration time, total duration of all measurements is estimated at 20 minutes per subject. No additional risks are to be expected. When possible, scar quality is assessed combined with a regular outpatient visit to the burn centre physician. In case a patient is willing to participate but unable to visit the outpatient department, the patient will be visited by a member of the research team.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

All patients included in LDI-trial
Complete LDI data of wound healing potential available and of wound healing
Informed consent

Exclusion criteria

Reconstructive surgery has been performed in all study wounds
Withdrawn informed consent for study participation to the preceding study and formally stopped participation to this study
Missing contact details

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	31-07-2014
Enrollment:	202
Type:	Actual

Ethics review

Approved WMO

Date:	21-05-2014
Application type:	First submission
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)

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	NL48539.101.14