Scar quality after tangential excision of burns

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20406

Source
Nationaal Trial Register

Brief title
HyCon

Health condition

Burns, Wound healing, Brandwonden

Sponsors and support

Primary sponsor: Vereniging Samenwerkende Brandwondencentra Nederland
Source(s) of monetary or material Support: Dutch Burns Foundation

Intervention

Outcome measures

Primary outcome

Scar quality 12 months post-surgery assessed by the observer score of the POSAS scale will be tested for normality before univariate analyses will be performed.

Secondary outcome

- To demonstrate increased dermal preservation in deep dermal burns after debridement with hydrosurgically versus conventional excision.

- To determine the minimal clinical important (MIC) change of the Patient and Observer Scar Assessment Scale (POSAS).

Study description

Background summary

Burn eschar is conventionally removed by tangential excision with a knife. This procedure is not only associated with substantial blood loss but also with unnecessary removal of viable dermis. During the last decade hydrosurgery has become popular in burn surgery. Hydrosurgery is generally thought to be a more precise and controlled manner of burn debridement leading to preservation of more dermal viable tissue and possibly to better scar quality. The objective of this study is to compare scar quality after conventional tangential excision versus hydrosurgical excision in patients with deep dermal burn wounds.

Study objective

The aim of this study is to assess long term scar quality of deep dermal burns after debridement with hydrosurgical excision versus conventional tangential excision.

Study design

- 3 months post surgery

- 6 months post surgery

- 12 months post surgery

Intervention

Hydrosurgery

Contacts

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Eligibility criteria

Inclusion criteria

Deep dermal burns that require excision and grafting

Exclusion criteria

- Burn wound < 50cm2

- TBSA > 30%

- Full thickness burns

- Chemical or electrical burns

- Infected wounds

- Patients that are unlikely to comply with requirement of the study protocol and follow-up

- No informed consent

Study design

Design

Study type:	Interventional
Intervention model:	Factorial
Allocation:	Randomized controlled trial

Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-01-2017
Enrollment:	137
Type:	Anticipated

Ethics review

Positive opinion

Date:	23-01-2017
Application type:	First submission

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
NTR-new	NL6085
NTR-old	NTR6232
Other	NL58875.101.16 ABR : METC 2016-66

Study results