Effectiveness of Dermal Substitution and Negative Pressure Wound Therapy in Burns: a Randomized Controlled Pilot Study

No registrations found.

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

Summary

ID

NL-OMON24206

Source
Nationaal Trial Register

Brief title
Glyaderm in Adult Burns (GAB)

Health condition

Burns

Sponsors and support

Primary sponsor: Not applicable.
Source(s) of monetary or material Support: Radboudumc

Intervention

Outcome measures

Primary outcome

Scar elasticity at 3, 6 and 12 months post-operatively

Secondary outcome

Graft take, epithelialisation, complications, scar pigmentation/vascularisation, POSAS observer/patient scale

Study description

Background summary

Split thickness skin grafts are the gold standard in the treatment of deep burns. Adding dermal substitution results in improved scar elasticity and scar quality. Unfavorable wound conditions in burns may however contribute to substitute degradation, limiting its effect. Previous studies showed improved substitute efficacy when combining dermal substitutes with negative pressure wound therapy (NPWT). The objective of this tstudy is to investigate the effect of a human-derived donor skin substitute Glyaderm when combined with negative pressure wound therapy in comparison to the gold standard treatment.

Study objective

Improved scar quality in burns treated with Glyaderm + STSG + NPWT

Study design

3, 6 and 12 months

Intervention

Glyaderm, split thickness skin graft and negative pressure wound therapy

Contacts

Public
Radboudumc
Elleke Munk

-
Scientific
Radboudumc
Elleke Munk

-

Eligibility criteria

Inclusion criteria

1. Deep dermal to full thickness burn wounds requiring excision and skin grafting
2. Age ≥18 years old
3. Two anatomically comparable wounds of ≥10 cm2 or one wound surface area of ≥64 cm2
4. Written informed consent

Exclusion criteria

1. Wounds not suitable for NPWT application
2. Solitary facial burns
3. Infected wounds
4. Patients suspected to be non-compliant, i.e. in case of severe cognitive dysfunction or psychiatric disorders
5. Pregnancy

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2021
Enrollment:	12
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	27-10-2021
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	NL9834
Other	METC Oost-Nederland : 2021-7412

Study results