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

Published: 26-10-2021
Last updated: 27-04-2024

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.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Skin and subcutaneous tissue therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON50928

Source
ToetsingOnline

Brief title
Glyaderm in Adult Burns

Condition

- Skin and subcutaneous tissue therapeutic procedures

Synonym
(deep dermal to full thickness) burn wounds

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,ETB-Bislife

Intervention

Keyword: Adult, Burns, Glyaderm, Scar quality

Outcome measures

Primary outcome

The main study endpoint is scar elasticity in the grafted burn wound sites at

3, 6 and 12 months post-operatively.

Secondary outcome

To investigate the effect of Glyaderm on graft take

To investigate the effect of Glyaderm on wound epithelialisation

To investigate the effect of Glyaderm on scar pigmentation and vascularisation.

To investigate incidence of burn wound infection by clinical evaluation and

taking bacterial swabs at certain time points

To investigate incidence of other complications

To investigate the effect of Glyaderm on scar quality as judged by an

experienced clinician using a validated questionnaire

To investigate the effect of Glyaderm on scar quality as judged by the patient

using a validated questionnaire

Study description

Background summary

Split thickness skin grafts are the gold standard in the treatment of deep burns. However, this often results in hypertrophic scarring and contractures, presumably due to a lack of dermal components. 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).

Study objective

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 design

An intra-individual, single-blinded, randomised controlled pilot trial.

Intervention

Application of Glyaderm, split thickness skin graft and NPWT versus split thickness skin graft and NPWT in two separate wounds or a split-scar model after randomisation.

Study burden and risks

Both treatments that participants can be allocated to are standard treatments. NPWT is also used regularly. There will be no extra burden for study participants in the frequency of follow-up visits. Study participants will have to complete a questionnaire regarding scar symptoms and undergo extra non-invasive scar measurements regarding elasticity and colour. There are no extra risks when participating in this study compared to regular treatment.

Contacts

Public
Radboud Universitair Medisch Centrum

Geert Grooteplein Zuid 10
Nijmegen 6525 GA
NL
Scientific
Radboud Universitair Medisch Centrum

Geert Grooteplein Zuid 10
Nijmegen 6525 GA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Deep dermal to full thickness burn wounds requiring surgery for wound healing/closure in adults.

Exclusion criteria

Wounds not suitable for negative pressure wound therapy application; solitary facial burns; infected wounds; patients suspected to be non-compliant, i.e.. in case of severe cognitive dysfunction or psychiatric disorders; pregnancy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-04-2023
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO

Date:	26-10-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL77058.091.21