

Prospective Case Series of Acute Complex Wounds Treated With Glyaderm

No registrations found.

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

Summary

ID

NL-OMON20860

Source

NTR

Brief title

ACW

Health condition

Acute deep dermal to full thickness skin and soft tissue defect(s) that will either not heal or take weeks to heal without grafting or (free) flap surgery.

Sponsors and support

Primary sponsor: Not applicable.

Source(s) of monetary or material Support: Radboudumc

Intervention

Outcome measures

Primary outcome

The main study endpoint is graft take in the grafted wound site(s) in a total follow-up of 12 weeks.

Secondary outcome

Wound epithelialisation 5-7 days after split skin graft placement.

Day of wound closure (>95% epithelialisation).

Incidence of complications: hematoma, graft loss, graft shift, post-operative bleeding, regrafting and wound infection.

Surgical and patient characteristics (timing (time in days between trauma and first reconstructive surgery); number of surgical debridements before reconstructive surgery, surgery duration, total body surface area (%) covered, length of hospital stay)

Subjective assessment of the scar after 12 weeks.

Study description

Background summary

Acute complex skin and soft tissue defects of different aetiologies can prove difficult to heal. Dermal substitutes can aid in wound closure of these defects. Glyaderm is a low-cost acellular dermal substitute derived from human cadaveric donors. It is often applied in deep dermal to full thickness burns requiring grafting for healing. Our aim is to investigate wound healing when applying Glyaderm in different acute complex skin and soft tissue defects.

Study objective

Acute complex skin defects will heal using a dermal substitute (Glyaderm).

Study design

Day -7 to -1: eligibility assessment, inclusion

Day 0: surgery

Day 5-7: graft take rate and wound epithelialisation rate assessment

Day x: >95% epithelialisation assessment

Week 12: subjective scar assessment

Intervention

Surgical application of Glyaderm and a split thickness skin graft in acute deep dermal to full thickness skin and soft tissue defects.

Contacts

Public

Radboudumc

Elleke Munk

Eligibility criteria

Inclusion criteria

1. Acute deep dermal to full thickness skin and soft tissue defect(s) that will either not heal or take weeks to heal without grafting or (free) flap surgery*.

2. Age ≥ 18 years old

3. Written informed consent

*These include, but are not limited to, donor sites of (free) flap harvest, defects after oncological resection, necrotising fasciitis and degloving injury.

Exclusion criteria

1. Active infection

2. Severe cognitive dysfunction or psychiatric disorders in patient history

3. Skin defects due to burns.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2021
Enrollment:	28
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion	
Date:	13-08-2021
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	NL9652
Other	METC Oost-Nederland : 2021-8206

Study results