Prospective Case Series of Acute Complex Wounds Treated With Glyaderm

Published: 18-08-2021
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To investigate the efficacy of the acellular dermal substitute Glyaderm on wound healing in various acute complex skin and soft tissue defects.

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

Summary

ID

NL-OMON51082

Source
ToetsingOnline

Brief title
Glyaderm in Acute Complex Wounds

Condition

- Skin and subcutaneous tissue therapeutic procedures

Synonym
deep wounds, full-thickness skin and soft tissue defects

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, Glyaderm, Soft tissue defect, Wound healing

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

Secondary study outcomes are:

- wound epithelialisation 5-7 days after STSG application;

- wound closure in days after STSG application

- complications: hematoma, graft loss/shift, postoperative bleeding,

regrafting, wound infection;

- patient and clinicians 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. When flap assisted closure is not an option, dermal substitutes can aid in wound closure of these defects. Glyaderm is a low-cost acellular dermal substitute derived from cadaveric human donors. It is applied in deep dermal to full thickness burns requiring grafting for healing. Further research is needed to explore the efficacy on wound healing when applying Glyaderm in different acute complex skin and soft tissue defects.

Study objective

To investigate the efficacy of the acellular dermal substitute Glyaderm on wound healing in various acute complex skin and soft tissue defects.

Study design

Prospective case series.

Intervention

Surgical application of Glyaderm and a split thickness skin graft in a one- or two-staged procedure.

Study burden and risks

There are no extra risks compared to regular treatment, which encompasses vacuum-assisted therapy and/or the direct application of split thickness skin grafts or free/local flap surgery. There will be no extra burden for study participants in the frequency of follow-up visits nor will any invasive measurements be performed. Accelerated wound closure may be expected in these wounds treated with Glyaderm.

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)

Inclusion criteria

Age >=18 years old

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

Exclusion criteria

Active infection
Severe cognitive dysfunction or psychiatric disorders in patient history
Burns

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	25-10-2021
Enrollment:	28
Type:	Actual

Ethics review

Approved WMO

Date:	18-08-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO Date:	20-10-2021
Application type:	Amendment
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	NL77377.091.21