Glyaderm in Pediatric Burns

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The aim of this study is to describe the scar quality in a paediatric burn population treated with Glyaderm up to 12 months after surgery.

Ethical review	Approved WMO
Status	Pending
Health condition type	Skin and subcutaneous tissue therapeutic procedures
Study type	Interventional research previously applied in human subjects

Summary

ID

NL-OMON57502

Source
Onderzoeksportaal

Brief title
Glyaderm in Paediatric Burns (GlyPeB)

Condition

- Skin and subcutaneous tissue therapeutic procedures

Synonym
Full-thickness burns

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Eerste geldstroom (geld van Ministerie van OC&W aan universiteiten)

Intervention

- Surigical procedure

Explanation

N.a.

Outcome measures

Primary outcome

Main study parameters/endpoints: The main study parameter is the scar quality measured with the Patient and Observer Scar Assessment Scale (POSAS) observer scale at 3, 6 and 12 months post-operatively.

Secondary outcome

To describe: - Graft take and wound epithelialization at 5-7 days postoperatively - Time to complete wound healing (>95% epithelialization) in days - Time to complete donor site healing in days - Wound/scar surface area at day of surgery and 3, 6 and 12 months post-operatively* - Scar quality using the POSAS patient scale, filled out by the parent at 3, 6 and 12 months post-operatively* - Quality of life using the TAPQOL (6 months to 24 months) or PedsQL (2-15 years) at 3, 6 and 12 months post-operatively. - Rate of scar hypertrophy during follow-up* - Rate of scar contractures during follow-up* - Range of motion (for affected joints) at 3, 6 and 12 months post-operatively* *if parents/patients are willing to extend their participation to 24, 36, 48 and 60 months, these variables will continue to be assessed.

Study description

Background summary

Rationale: The gold standard for treatment of deep dermal to full thickness burns is surgical excision of the eschar followed by skin transplantation with split thickness skin grafts to replace lost epidermis. Dermal substitutes are increasingly used in the treatment of deep dermal to full thickness burns to replace lost dermis. The acellular dermal substitute Glyaderm is of human origin. Its application has not been described in a solely paediatric population before. Objective: To describe scar maturation and quality when applying Glyaderm in deep dermal to full thickness burns in a pediatric population.

Study objective

The aim of this study is to describe the scar quality in a paediatric burn population treated with Glyaderm up to 12 months after surgery.

Study design

Study design: Prospective case series. Study population: Children and adolescents aged ≤15 years old.

Intervention

Intervention: Application of Glyaderm in combination with an autologous split thickness skin graft on debrided deep dermal or full thickness burn wounds.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Follow-up appointments for the study are similar to those in standard of care. Parents are asked to fill out the POSAS for the scars of their children and a quality of life scale for their children at 3, 6 and 12 months. Children aged 5 years and older are also asked to fill out a questionnaire on their quality of life.

Contacts

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Trial sites

Trial sites in the Netherlands

Radboud Universitair Medisch Centrum
Target size: 20

Listed location countries

Netherlands

Eligibility criteria

Age
Babies and toddlers (28 days-23 months)
Children (2-11 years)
Adolescents (12-15 years)

Inclusion criteria

Full-thickness burn

Pediatric (< 16 years)

Informed consent by parents (<12 years) or parents and patient (12-15 years old)

Exclusion criteria

No informed consent
Burn wound < 30 cm2
Clinically infected wounds

Study design

Design

Study phase:	N/A
Study type:	Interventional research previously applied in human subjects
Intervention model:	Single
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	20-10-2022
Enrollment:	20
Duration:	12 months (per patient)
Type:	Anticipated

Medical products/devices used

Product type:	N.a.

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N.a.

Ethics review

Approved WMO

Date:	08-04-2025
Application type:	First submission
Review commission:	METC Oost-Nederland

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
ClinicalTrials.gov	NCT05309720
Research portal	NL-009758