Clinical Application of a Dermal Substitute based on glycerol preserved Allograft: GLYADERM® A multicentre, prospective, controlled, randomized, comparative trial of Glyaderm® and split thickness skin graft versus split thickness skin graft alone in full thickness skin defects

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Objective: The main objective is to evaluate the difference in scar quality, after skin restoration of full thickness defects treated with Glyaderm® and STSG versus STSG alone.Secondary objectives are: to evaluate the percentage of Glyaderm® take...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Injuries NEC
Study type	Interventional

Summary

ID

NL-OMON36554

Source
ToetsingOnline

Brief title
Multicentre evaluation Glyaderm®

Condition

- Injuries NEC
- Skin and subcutaneous tissue therapeutic procedures

Synonym
burn wounds, full thickness skin defects

Research involving
Human

Sponsors and support

Primary sponsor: Euro Tissue Bank
Source(s) of monetary or material Support: Euro Skin Bank;derde geldstroom; Euro Skin Bank is een non profit stichting verbonden aan de Nederlandse Brandwonden Stichting.

Intervention

Keyword: Glyaderm®, Scar, Transplantation, Wound healing

Outcome measures

Primary outcome

Scar elasticity 12 months post wound healing

Secondary outcome

1. percentage of Glyaderm® take before application of autografts,

2. healing time and percentage of autograft survival

3. bacterial load

4. scar quality, objective and subjective assessments

4. cost*effectiveness and health related quality of life study (i.e. cost

utility analysis).

Study description

Background summary

Rationale:
The healing of full thickness skin defects that are treated with a split thickness skin graft (STSG), is frequently associated with excessive scarring and contraction.
The psychological burden of sometimes extremely poor cosmesis of these scarred regions as well as functional problems due to skin tightness and decreased joint mobility cause a very significant morbidity in these patients. The most commonly used dermal substitute Integra has proven to be efficacious in early clinical trials but lacks elastin which is an important constituent of dermis and enhances its pliability and function. The long term benefit of the use of Integra® and the susceptibility to infection makes its use somewhat controversial and operator dependant. Integra® and other dermal substitutes are highly commercialized products which harbours great costs and for that reason often not affordable for a lot of patients. We think that Glyaderm® will have at least the same advantages as Integra and due to the elastin in this substitute it will contribute to a long term improvement of pliability and function and a better esthetic outcome. Due to a lower price it should be affordable for all burn patients.

Study objective

Objective:
The main objective is to evaluate the difference in scar quality, after skin restoration of full thickness defects treated with Glyaderm® and STSG versus STSG alone.
Secondary objectives are: to evaluate the percentage of Glyaderm® take before application of autografts, to compare healing time and percentage of autograft survival and bacterial load in full thickness defects treated with Glyaderm® and STSG versus STSG alone, and to conduct a concurrent cost*effectiveness and health related quality of life study (i.e. cost utility analysis).

Study design

This will be an interventional, prospective, randomized and controlled interactive web based, study in a multicentre setting.

Intervention

All included patients will undergo full thickness removal of the burned skin or adequate debridement of all necrotic tissue. The wounds of the patients will be covered with glycerol preserved allografts for wound bed preparation.
At the second operation, 5-7 days after the first operation, the allografts are removed. If the wound bed is not suitable for grafting, additional wound bed preparation with allografts is required until the wound bed is satisfactory. If the wound bed is suitable for grafting, the patient is randomized to the Glyaderm® group or the control group.

The wounds of the patients randomized to the Glyaderm® group are covered with Glyaderm®. After 6-8 days the wounds are finally covered with a thin STSG. In the control group, the wounds are immediately covered with a thin STSG.

Study burden and risks

The burden for the patients participating in this study consist of extra operations for patients, two in the index group and one in the control group. These extra operations however will be done as much as possible in combination with regular operations for other wounds by selection of patients with multiple wounds needing skin grafts. Extra burden post surgery is represented by the fact that patients entering this study will be evaluated more extensively during the inpatient period and outpatient follow up visits at 1,6 and 12 months after wound healing. This will take approximately 3 hours of their time in total. Additional risks related to this study are the normal risks for a surgical procedure as performed for any other burn patient needing skin grafts.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• All clearly full thickness burns or skin defects (TBSA Full Thickness Burn < 30%) as clinically evaluated by two plastic surgeons and/or specialist burn surgeons
• Possibility to follow the complete treatment schedule until final graft take and subsequently wound healing and finally participation in the follow-up schedule
• Informed consent has been obtained

Exclusion criteria

•All partial thickness burns that can heal by conservative treatment
•Patients younger than 18 years of age
•TBSA > 30 %
•Study wound smaller than 100 cm² or greater than 800cm2.
•No follow-up till wound closure or withdrawal before start of follow-up
•Patient has any condition(s) that seriously compromises the patient*s ability to complete this study
•Patient has participated in another study utilizing an investigational drug within the previous 30 days
•Patient has one or more medical condition(s), diabetes, including renal, hepatic, hematologic, neurologic, or immune disease that in the opinion of the investigator would make the patient an inappropriate candidate for this study

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-10-2011
Enrollment:	36
Type:	Actual

Ethics review

Approved WMO Date:	02-03-2011
Application type:	First submission
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)
Approved WMO Date:	07-10-2011
Application type:	Amendment
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)

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	NL34440.101.10

Study results

Date completed: 15-05-2014

Actual enrolment: 2

Summary results
Trial is onging in other countries