Epidermal skin grafting: does it improve wound healing?

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Ethical review	Approved WMO
Status	Pending
Health condition type	Epidermal and dermal conditions
Study type	Interventional

Summary

ID

NL-OMON54865

Source
ToetsingOnline

Brief title
Epigrafting

Condition

- Epidermal and dermal conditions

Synonym
chronic wound; skin cancer

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: donor site, skin, ulcer, wound

Outcome measures

Primary outcome

Primary question:

Does Epidermal Skin Grafting affect the wound healing of patients with acute and chronic wounds?

The outcome measure of wound healing contains two variables, duration to total epithelialization and surface reduction per unit time. Both are measured using digital photography and independent assessment (total epithelialization) and digital photo analysis using the WHAT software (surface reduction).

In the acute wound group without SSG, we expect faster wound healing by the ESG in the secondary healing donor site compared to the control group. In the acute and chronic wound group that is indicated for SSG, the ESG group is expected to display identical healing tendency as the SSG-receiving control group, but the benefit is in pain perception, more limited or absent appearance of the scar and an increased quality of life.

Secondary outcome

Secondary questions:

• What is the influence of ESG on the pain intensity of the donor and acceptor site during the treatment process? Pain is measured with NRS (Numeric Rating Scale) score

• What is the quality of the scar of the secondary healing wound with ESG compared to the control group? The quality of the scar is measured with the

validated POSAS method, whereby both the patient and the doctor give an opinion on, among other things, the redness, itching, swelling, lumpiness and pain of scars.

• What is the influence on the patient's quality of life of both treatment routes? Quality of life is measured with the validated scales EQ5D (generic) and the Wound QoL (wound specific).

Study description

Background summary

Autologous skin grafting, such as a split skin graft (SSG), is a well-known plastic surgical intervention to close wounds. While effective, this treatment requires a trained surgeon to use anesthesia, an operating room, and makes a wound at the donor site. Sometimes this intervention is not an option, e.g. in the face, because of the poor aesthetic result. These drawbacks can be overcome by using epidermal skin grafts, which can be harvested and transplanted at an outpatient clinic, without anesthesia and with minimal to no scarring at the donor site: Epidermal skin grafting (ESG). ESG is the transplantation of autologous epidermal cells from a donor site to a wound (acceptor site), to promote wound healing in patients with secondary healing wounds. However, this application hardly is not followed at the time because harvesting sufficient epidermal cells is not easy. Recently, a new epidermal cell harvesting device (CelluTome; Kinetic Concepts, Inc, San Antonio, Texas) is on the market. The device creates epidermal micrografts with minimal damage to the donor site and minimal pain during and after graft harvesting. Moreover, ESG does not require an operating room and hospitalization. This harvester, which simultaneously applies both heat and negative pressure to normal skin, is used to produce epidermal micrografts that subsequently are placed on the wound. Observational studies unanimously point to a positive effect on wound healing. However, since most wounds tend to heal, it is still unknown to what extent the healing effect can be attributed to ESG because comparative studies into the effectiveness of ESG are lacking.

Study objective

The aim of this study is to determine whether the alleged positive effects of ESG on acute surgical wounds as well as ESG effects on chronic wounds are

attributable to this intervention.

Study design

Study design:
Open-label randomized controlled trial.
The open-label design is unavoidable because the intervention is a different (in the acute- and chronic wound group indicated for SSG), or an additional (in the acute wound group indicated for secondary healing), procedure to the standard treatment. We aim to randomize the effectiveness of ESG compared to standard treatment and choose two homogeneous populations of chronic- and acute wound patients.

Study duration:
We expect to have included the required number of patients 18 months after the start. This does not include the 6-month long-term follow-up during which the patient is called.

Setting:
Acute wound patients with a secondary healing donor site: Department of Plastic and Reconstructive Surgery at Erasmus MC. The ESG starts 1 week after the intervention.
Chronic wound patients who need wound coverings: Department of Dermatology of Erasmus MC.

In both cases, the Nursing Specialist Wounds (VS-w) carries out the ESG in the outpatient clinic.

Intervention

ESG is the intervention in both groups. ESG is a one-time transplant of epidermal cells from elsewhere on the patient's body (the donor site) to the wound (the acceptor site).
• In the acute wound group, the intervention group will receive an ESG at the 1st outpatient visit 1 week after surgery. The control group will either receive a SSG or secondary wound healing as indicated by the surgeon.
• In the chronic wound group, the intervention group receives an ESG and the control group an SSG.

Study burden and risks

Patient burden:
- extra time for a single ESG administration: 30 min.
- extra time for taking a wound photo (donor site), filling in the questionnaires (EQ5D and Wound QoL, VAS pain and POSAS scar scale (the POSAS is also completed by the practitioner): 4x 15 min.

Risk:
no risks: CE marked device is used within the marketing authorization area.

If the ESG (the harvested epithelial cells) don t have a take in the wound, then:
- the acute wound group, indicated for secondary, healing further will undergo secondary healing (equal to the control group).
- the acute wound group, indicated for SSG, will receive a SSG (equal to the control group).
- the chronic wound group, indicated for SSG, misses the supposed value of the ESG treatment and then will receive an SSG (equal to the control group)

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 patients who are sheduled to receive a skin transplant following skin cancer excision surgery; all patients suffering from a chronic ulcer who are sheduled to receive a SSG (split skin graft)

Exclusion criteria

-the patient suffers from an oncologic ulcer in the wound area
-the patient is known with alcohol or drug abuse
-the patient cannot be informed correctly (e.g. because of language or mental problems)
-the patient is unable to travel to the outpatient clinic for follow up visits

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2020
Enrollment:	140
Type:	Anticipated

Medical products/devices used

Generic name:	CELLUTOME Epidermal Harvesting System
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	18-12-2020
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	26-01-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (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	NL74036.078.20