Application of cultured autologous keratinocytes in combination with a meshed split skin autograft for burn wound healing

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ObjectiveEvaluation of the application of cultured autologous keratinocytes in combination with a meshed split skin autograft to improve burn wound healing

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

Summary

ID

NL-OMON35395

Source
ToetsingOnline

Brief title
Cultured keratinocytes for burn wound treatment

Condition

- Epidermal and dermal conditions

Synonym
deep (third degree) burn wounds

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum
Source(s) of monetary or material Support: Subsidie Nederlandse Brandwonden

Stichting project nummer 07.116

Intervention

Keyword: burn wounds, keratinocytes, split skin transplantation

Outcome measures

Primary outcome

The % of wound closure after 7 days. Wound closure will be monitored by an experienced surgeon. The exact area will be assessed using computerized planimetric determination.

Secondary outcome

Scar quality at three and 12 months after operation will be assessed using the POSAS, cutometer to measure scar elasticity, dermaspectometer to assess scar colour and Primos 3D to assess the smoothness of the scar.

Study description

Background summary

Background
Healing of large full thickness burn wounds is still accompanied by scar formation. Even standard treatment, transplantation with a (meshed) split skin autograft, does not result in satisfactory functional and cosmetic appearance of the healed wound.
Limited donorsite availability in combination with large wound areas can make it necessary to use widely meshed grafts or to use the Meek-Wall technique. Bigger enlargements of meshes give more scarring, probably because wound closure still needs several weeks. Application of cultured keratinocytes could enhance wound closure.
In an animal study we demonstrated that the application of cultured keratinocytes seeded on a carrier indeed enhanced wound closure.

Study objective

Objective

Evaluation of the application of cultured autologous keratinocytes in combination with a meshed split skin autograft to improve burn wound healing

Study design

Study method
After an intitial trial period to fine tune the protocol, a prospective, multicentre, randomised trail will be carried out in which an intra-patient comparisson will be made of the effect of treatment with cultured autologous keratinocytes in combination with split skin autograft, and split skin graft alone in adult patients with acute fullthickness burn wounds.
The keratinocytes will be isolated from a biopsy obtained from unaffected skin (3 cm2) and cultured to increase the cell numbers. The expanded keratinocytes will be seeded on a collagen carrier and transplanted onto the enlarged autograft after debridement of the wound, approximately 2 weeks after the biopsy was taken.
Wound healing is monitored during normal dressing changes. Primary outcome measure is percentage of wound closure after 7 days (measured by planimetry)

Intervention

Within the first few day after admission to the burn centre a biopsy (approx. 3 cm2) is taken from the unaffected skin and taken to the lab for the culture of the keratinocytes. After two weeks the patient will be operated, and both wounds will be transplanted with a meshed split skin autograft. One wound/wound area (randomly assigned) will subsequently be cover with the carrier containing the cultured autologous keratinocytes.

Study burden and risks

An extra wound is created to obtain healthy skin for keratinocyte culture. The biopsy as taken under anaesthetics and the wound is sutured. The pain will be combated with pain relievers (which the patient most probably receive anyhow) and possible bacterial infection will be treated with antibiotics.
The evaluation of the wounds and scars will take more time especially the outpatient follow-up at 3 and 12 months. This will take approximately 30 minutes more than usual.
A possible risk will be intolerance or an allergic reaction to one of the tissue culture ingredient. The carrier is rinsed in saline prior to the application to remove the culture medium.
We anticipate that the experimental treatment results in improved wound healing with better cosmetic and functional properties. This even might lead to less secondary reconstructive surgery.

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

-competent and temporarily incompetent patients 18 years of age or older with acute burn wounds that require widely meshed skin grafting, which do not need immediate excision
- minimal study wound area 100 cm2
- maximal study wound area 300 cm2
- maximal TBSA 50% full thickness wounds
-Informed consent

Exclusion criteria

- Immunocompromised patients
- Infected wounds

- Use of high doses of (.20mg/pd) corticosteroids and/or cytostatica
- Known penicillin allergy
- Conditions where the patient is non compliant as judged by a medical specialist

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-06-2008
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	Application of cultured keratinocytes on a collagen (Matriderm) carrier to improve healing of burn w
Registration:	Yes - CE outside intended use
Product type:	Medicine
Generic name:	Somatic cells autologous

Ethics review

Approved WMO

Date:	02-08-2007

Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	07-02-2008
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	09-06-2010
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	15-11-2010
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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
EudraCT	EUCTR2007-004296-19-NL
CCMO	NL19048.000.07