OTR4120: topical application at split-skin graft donor sites. A clinical evaluation of cicatrisation.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27325

Source
Nationaal Trial Register

Brief title
OTR4120 application to skin graft donor sites.

Health condition

Healing of split-skin graft donor site.

Sponsors and support

Primary sponsor: Department of Plastic and Reconstructive Surgery
Source(s) of monetary or material Support: Dutch Burns Foundation

Intervention

Outcome measures

Primary outcome

Clinical improvement of the donor site wound, measured as reduction in wound size in time.

Secondary outcome

1. Complete healing of the wound, measured as the time needed for complete healing.

2. Improvement of the quality of the (former) wound area to be measured as the amount of vascularisation, scar formation, skin pigmentation and elasticity.

3. Pain reduction.

4. Itch reduction.

Study description

Background summary

This study aims to investigate, in a double blinded, randomized controlled trial, the effectiveness of treatment of split-skin graft donor sites with a new product, in which a regenerating agent (RGTA), made of sugar, reactivates at very low doses our natural regeneration potential. In total, 19 patients with split-skin graft donor sites will be included. The product will be applied for only 5 minutes and removed. This is enough for this sugar to bind and to protect the matrix proteins of the wound bed and to allow the tissue to repair. This treatment will be followed by standard care. Patient follow-up is 12 weeksThe study is for a duration of 12 weeks for each patient. From preliminary studies improved healing characteristics and a reduction in time to complete healing and pain are expected without any side effects.

Study objective

OTR4120 will improve healing of split-skin graft donor sites.

Study design

Day 7, Day 12, Week 12

Intervention

Intra-patient trial: split-skin donor site is dived into 3 parts. Proximal and distal receive placebo or OTR4120-treatment. Middle part is non-treated to prevent carry-over effects.

For the OTR4120-treated part of the split-skin graft donor site, the medical device Cacipliq20 consists of a sterile solution of OTR4120 (100 microgram/ml in physiological salt).

For the placebo-treated part of the split-skin graft donor site, the medical device Cacipliq20 consists of a sterile solution of physiological salt.

Contacts

Public
Dept of Plastic Surgery, Ee15.91
's Gravendijkwal 230

J.W. Neck, van
Rotterdam 3015 CE
The Netherlands
+31 10 704 3303
Scientific
Dept of Plastic Surgery, Ee15.91
's Gravendijkwal 230

J.W. Neck, van
Rotterdam 3015 CE
The Netherlands
+31 10 704 3303

Eligibility criteria

Inclusion criteria

1. Signed informed consent;

2. Aged over 18 yrs;

3. Patients in need of an autologous skin graft;

4. Adequate nutritional state;

5. Adequate immuno-competence;

6. Regulated diabetes mellitus;

7. Women in reproductive age take contraceptive medication.

Exclusion criteria

1. Minor patients;

2. Pregnant or breastfeeding women;

3. Patient involved in another clinical trial, currently or less that 1 month before participation in this study;

4. Size of split-skin graft donor site is less than 7x18 cm;

5. Patients unable to sign the informed consent;

6. Patients unable to indicate their level of pain and itch;

7. Uninsured patients.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2009
Enrollment:	19
Type:	Anticipated

Ethics review

Positive opinion

Date:	08-01-2009
Application type:	First submission

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
NTR-new	NL1548
NTR-old	NTR1619
Other	MEC Erasmus MC : 2008-374
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A