

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

Gepubliceerd: 08-01-2009 Laatste bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27325

Bron

Nationaal Trial Register

Verkorte titel

OTR4120 application to skin graft donor sites.

Aandoening

Healing of split-skin graft donor site.

Ondersteuning

Primaire sponsor: Department of Plastic and Reconstructive Surgery

Overige ondersteuning: Dutch Burns Foundation

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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 weeks. The 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.

Doel van het onderzoek

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

Onderzoeksopzet

Day 7, Day 12, Week 12

Onderzoeksproduct en/of interventie

Intra-patient trial: split-skin donor site is divided 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 Caciqliq20 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 Caciqliq20 consists of a sterile solution of physiological salt.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Minor patients;
2. Pregnant or breastfeeding women;
3. Patient involved in another clinical trial, currently or less than 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Dubbelblind
Controle:	Placebo

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-02-2009
Aantal proefpersonen:	19
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	08-01-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1548
NTR-old	NTR1619
Ander register	MEC Erasmus MC : 2008-374
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten

N/A