OTR4120: topical application at venous ulcers. A clinical evaluation of cicatrisation.

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OTR4120 will improve healing of chronic ulcers.

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

Samenvatting

ID

NL-OMON21990

Bron
Nationaal Trial Register

Verkorte titel
OTR4120 application to venous ulcers

Aandoening

ulcer
venous
chronic

Ondersteuning

Overige ondersteuning: Initiator and sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Clinical improvement of the investigated ulcers, measured as the reduction of the wound

area in time.

Toelichting onderzoek

Achtergrond van het onderzoek

Venous ulcers are, in aging Western societies, an increasing problem and display a significant impact on the quality of life of patients and on health economics.

This study aims to investigate, in a double blinded, randomized controlled trial, the effectiveness of treatment of chronic wounds (venous ulcers) with a new product, in which a regenerating agent, made of sugar, reactivates at very low doses our natural regeneration potential. In total, 70 patients with venous ulcers (>6 months open with no or insufficient signs of healing) will be included. The ulcer(s) will be cleaned and the product will be applied for only 5 minutes and removed. This is enough to this sugar to stabilize the wound and to allow the tissue to repair. This treatment will be followed by standard care. The study is for a duration of 16 weeks for each patient. From preliminary studies a dramatic reduction of ulcer size, time to complete healing and pain are expected without any side effect.

Doel van het onderzoek

OTR4120 will improve healing of chronic ulcers.

Onderzoeksopzet

week: 0,5; 1; 1.5; 2; 2.5; 3; 3.5; 4; 6; 8; 10; 12; 14; 16.

Onderzoeksproduct en/of interventie

For the OTR4120-group, the medical device Cacipliq20 consists of a sterile solution of OTR4120 (100microgram/ml) in physiological salt.

For the placebo group the medical device Cacipliq20 consists of a

sterile solution of physiological salt.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Signed informed consent.

2. Age at least 18 years.

3. Women at a reproductive age should use birth control during the entire study period

4. Patients must have a venous ulcus cruris present for at least 6 months and scored according the PUSH tool (score at least 4).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Minor aged patients.

2. Pregnant or breast-feeding women.

3. Inclusion in another clinical trial in the 4 weeks preceeding this study and/or during this study.

4. Patients who, because of personal circumstances are unable to comply to the study visit scheme.

5. Patients who, because of mental limitations, are unable to visualise the degree of pain and itch of the ulcer.

6. Patients unable to sign the informed consent.

7. Uninsured patients.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	17-03-2008
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	04-03-2008
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	NL1197
NTR-old	NTR1242
Ander register	METC : 2007-244
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A