An open, randomized, (out-patient-) clinical study into the effectiveness, durability and cost efficiency of Tiscover (cultured, autologous skin) for chronic leg wounds (ulcera cruris).

Gepubliceerd: 14-10-2005 Laatst bijgewerkt: 18-08-2022

We hypothesize that ulcers treated with Tiscover will significantly decrease in size resulting in most cases in full healing, compared to the control group which is not treated with Tiscover.

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

Samenvatting

ID

NL-OMON27551

Bron
Nationaal Trial Register

Verkorte titel
TISCOVER

Aandoening

ulcera cruris venosa, ulcera cruris arterio(lo)scleroticum and ulcers of mixed origin

Ondersteuning

Primaire sponsor: NWO-Biopartner First Stage Grant
Overige ondersteuning: Dermatology
VU University Medical Center
De Boelelaan 1117
1081 HV Amsterdam

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Effectiveness of treatment of therapy resistent, chronic ulcera cruris (>5 months open; >2 months with no sign of healing), with Tiscover.

Toelichting onderzoek

Achtergrond van het onderzoek

An open, randomized, multicenter trial into the effectiveness of treatment of chronic wounds (ulcera cruris) with a new skin substitute. Tiscover is an autologous full-thickness skin substitute of 3 cm2. Recently 19 ulcers have been treated with Tiscover and in more than 60% of the cases complete closure occured within 8 weeks, without any side effects.
In total, 100 patients with ulcera cruris venosa, ulcera cruris arterio(lo)scleroticum or mixed origin (>6 months open; > 2 months with no sign of healing; size 5-100 cm2) will be included. They will be divided into an in-patient (n=40)and an out-patient (n=60) group - each consisting of a test and a control group. In the in-patient and out-patient groups, the wounds will be prepared with Vacume Assisted Closure therapy or acellula allodermis respectively. In the test group, Tiscover will then be applied and all groups will receive continued compression therapy. The reduction in ulcer size will be measured.
Statistical analysis: Two group continuity corrected c2 test with a 2 sided p-value of <0.050 being significant
The study is for a duration of 24 weeks for each patient.

Doel van het onderzoek

We hypothesize that ulcers treated with Tiscover will significantly decrease in size resulting in most cases in full healing, compared to the control group which is not treated with Tiscover.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Two out-patient groups:

Control group (n=30): 1 week prior wound bed preparation with acellular allodermis;

Test group (n=30):1 week prior wound bed preparation with acellular allodermis followed by removal of allodermis and application of Tiscover;

Two in-patient groups:

Control group (n=20): 5 day prior wound bed preparation with Vacume Assisted Closure therapy (VAC);

Test group (n=20):5 day prior wound bed preparation with VAC followed by application of Tiscover.

All patients receive compression therapy.
All patients have a weekly followup for the duration of 24 weeks.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Ulcus cruris venosum, ulcus cruris arterio(lo)scleroticum and ulcers of mixed origin;

2. Non-vital ulcers which exist for at least 5 months and which do not respond to adequate compression therapy and local wound treatment;

3. Ulcers between 5 and 100 square centimeters;

4. Signed informed consent;

5. Ankle / arm index >0.7.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Diabetic foot ulcers;

2. Serious co-morbidity which decreases the life expectancy to less than 2 years;

3. Use of high doses of corticosteroids and/or cytostatic drugs (>20 mg/day);

4. Diagnosed Penicillin allergy;

5. Serious infection of the ulcer bed at time t=0;

6. Disturbances of psychiatric nature where the following of medical advice becomes a problem;

7. Declining clinical treatment and/or follow up visits.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd

Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	15-10-2005
Aantal proefpersonen:	100
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	14-10-2005
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	NL399
NTR-old	NTR439
Ander register	: N/A
ISRCTN	ISRCTN86386707

Resultaten

Samenvatting resultaten
N/A