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).

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27551

Source
Nationaal Trial Register

Brief title
TISCOVER

Health condition

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

Sponsors and support

Primary sponsor: NWO-Biopartner First Stage Grant
Source(s) of monetary or material Support: Dermatology
VU University Medical Center
De Boelelaan 1117
1081 HV Amsterdam

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

1. Determine whether hospitalization and wound bed preparation have a beneficial effect;

2. Evaluate unforeseen toxicity due to Tiscover treatment;

3. Evaluate the durability of treatment with Tiscover;

4. Determine whether out-patient treatment with Tiscover is possible;

5. Compare the costs of Tiscover treatment with present costs for caring/treatment of inert ulcera cruris without Tiscover.

Study description

Background summary

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.

Study objective

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.

Study design

N/A

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-10-2005
Enrollment:	100
Type:	Actual

Ethics review

Positive opinion

Date:	14-10-2005
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	NL399

Register	ID
NTR-old	NTR439
Other	: N/A
ISRCTN	ISRCTN86386707

Study results

Summary results
N/A