

# 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)

<b>Submission date</b> 27/01/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 27/01/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 14/08/2009	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr E.M. Boer, de

### Contact details

VU University Medical Center  
Department of Dermatology  
De Boelelaan 1117  
Amsterdam  
Netherlands  
1081 HV  
+31 (0)20 4444444  
em.dboer@vumc.nl

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

NTR439

# Study information

## Scientific Title

## Acronym

TISCOVER

## Study objectives

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®.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Received from local medical ethics committee

## Study design

Multicentre randomised open label active controlled parallel group trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied

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

## Interventions

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 Vacuum 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 follow-up for the duration of 24 weeks.

### **Intervention Type**

Other

### **Phase**

Not Specified

### **Primary outcome measure**

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

### **Secondary outcome measures**

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®

### **Overall study start date**

15/10/2005

### **Completion date**

15/10/2007

## **Eligibility**

### **Key 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 cm
4. Signed informed consent
5. Ankle/arm index >0.7

### **Participant type(s)**

Patient

### **Age group**

Not Specified

### **Sex**

Not Specified

### **Target number of participants**

**Key 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

**Date of first enrolment**

15/10/2005

**Date of final enrolment**

15/10/2007

**Locations****Countries of recruitment**

Netherlands

**Study participating centre**

VU University Medical Center

Amsterdam

Netherlands

1081 HV

**Sponsor information****Organisation**

VU University Medical Centre (VUMC) (Netherlands)

**Sponsor details**

Department of Dermatology

De Boelelaan 1117

Amsterdam

Netherlands

1081 HV

**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/00q6h8f30>

# Funder(s)

## Funder type

Research council

## Funder Name

The Netherlands Organisation for Scientific Research (Nederlandse Organisatie voor Wetenschappelijk Onderzoek [NWO]) (Netherlands) Biopartner First Stage Grant

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration