

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)

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

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®

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration