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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

Registration date
27/01/2006

Last Edited
14/08/2009

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] 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
Ulcera cruris venosa, ulcera 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