a pilot study into the effects and feasibility of the use of Tiscover® (tissue-engineered autologous skin substitute) for chronic ulcers (venous ulcers, diabetic ulcers and decubitus ulcers).

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to determine the efficiency and feasibility of an autologous tissue engineered skin substitute in healing chronic ulcers (decubitus-, diabetes foot- and venous- ulcers) compared to usual wound care therapies (e.g.: off-loading, wound cleansing,...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Skin and subcutaneous tissue disorders NEC
Study type	Interventional

Summary

ID

NL-OMON30845

Source
ToetsingOnline

Brief title
Effects of Tiscover® on chronic ulcers

Condition

- Skin and subcutaneous tissue disorders NEC

Synonym
decubitus/diabetic/ venous ulcers

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: innovatiefonds en verpleeghuizen gezamenlijk

Intervention

Keyword: diabetic ulcer, pressure ulcer, skin substitute, venous ulcer

Outcome measures

Primary outcome

% decrease of ulcer

Secondary outcome

pain, quality of life, satisfaction patient and caregivers

Study description

Background summary

Chronic ulcers are very prevalent in vulnerable aged patients in long term care settings. These ulcers are often very persistent, have a negative impact on quality of life and are a burden to both patient and care giver.

Study objective

to determine the efficiency and feasibility of an autologous tissue engineered skin substitute in healing chronic ulcers (decubitus-, diabetes foot- and venous- ulcers) compared to usual wound care therapies (e.g.: off-loading, wound cleansing, compression). The study population is elderly patients residing in long term care facilities.

Study design

Patients with hard to heal ulcers persisting for more than 4 weeks, size 1 * 100 cm2 and showing no tendency to heal will be included. Ulcers are decubitus ulcers (stage II-III), diabetic foot ulcers (grade 1-3), and venous ulcers. The number of patients to be included is 20. These patients will receive skin

substitute after prior wound bed preparation with vacuum assisted closure therapy.

Intervention

application of an autologous tissue engineered skin substitute

Study burden and risks

Tiscover is an autologous product, it is cultured in a sterile environment and there is an extended quality control program, which makes side-effects and risks not to be expected.
Observation in earlier and ongoing treatments acknowledges this.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

· Venous ulcer, arterio(lo)sclerotic ulcer , decubitus ulcer or diabetic ulcer .
· chronic (>1 month no tendency to heal),
· Ulcer 1-100 cm^2
· consent (competent)
· Ulcus depth < 1.0 cm

Exclusion criteria

- serious comorbidity (lief expectancy < 6 months)
- use of high dose corticosteroids or cytostatics
- allergy for penicillin
- serious wound infection at t=0
- refusal of necessary clinical treatments
- incompetent for decision making

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Will not start
Start date (anticipated):	01-03-2007
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL16543.029.07