DenovoDerm phase I. A phase I, open, prospective, multicentric study to evaluate the safety of autologous tissue-engineered dermal substitutes for the treatment of large deep-partial and full-thickness skin defects

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To evaluate the safety of an autologous cellular collagen hydrogel-based skin graft (denovoDerm) in patients with skin defects that require definitive therapeutic coverage. DenovoDerm can be transplanted together with an STSG to cover a full...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Epidermal and dermal conditions
Study type	Interventional

Summary

ID

NL-OMON44654

Source
ToetsingOnline

Brief title
Treatment of skin defects with dermal skin substitutes

Condition

- Epidermal and dermal conditions
- Skin and subcutaneous tissue therapeutic procedures

Synonym
deep wounds, Full thickness skin defects

Research involving
Human

Sponsors and support

Primary sponsor: Universität Zürich
Source(s) of monetary or material Support: ZonMw,Nederlandse Brandwonden Stichting

Intervention

Keyword: Full thickness skin defects, Phase 1, Skin substitutes, Tissue engineering

Outcome measures

Primary outcome

The primary outcome variables for safety are the rate of local infection and graft take.

The rate of local infection will be evaluated 4-6 days after transplantation of denovoDerm and at 21 ±1 days after transplantation. This will be evaluated with clinical andmicrobial characteristics by an experienced (plastic) surgeon or medical researcher.

Graft take will be evaluated 21 ±1 days after transplantation in a standardized fashion by an experienced (plastic) surgeon or medical researcher. Graft take will be depicted as a percentage of transplanted area.

Secondary outcome

The secondary outcome variable is the number of adverse events. This will be evaluated during clinical admission to the hospital and during outpatient visits.

Study description

Background summary

The functionally and cosmetically best therapeutic option for the treatment of full thickness skin defects would be transplanting full thickness autologous skin, as this basically leads to reconstruction of a perfectly normal skin in terms of both function and cosmesis. However, donor site availability is limited with respect to size and donor site morbidity, and the coverage of extended lesions therefore still poses a very significant challenge. The standard therapy for full thickness wounds is transplantation with a split thickness skin graft (STSG). The surgical treatment with STSG often results in disappointing scar quality. The use of a dermal skin substitute could improve outcome of scars.

Study objective

To evaluate the safety of an autologous cellular collagen hydrogel-based skin graft (denovoDerm) in patients with skin defects that require definitive therapeutic coverage. DenovoDerm can be transplanted together with an STSG to cover a full thickness skin defect. DenovoDerm can be grafted in a single-step procedure.

Study design

A multinational phase I clinical trial will be conducted at the VU University Medical Centre in Amsterdam, the Red Cross Hospital in Beverwijk and the Kinderspital, a Swiss pediatric burn centre in Zurich, in collaboration with the respective departments of plastic, reconstructive and hand surgery.

Intervention

The use of a dermal (combined with a STSG) cellular collagen hydrogel-based skin graft on a full thickness skin defect.

Study burden and risks

The burden for the participating patients is minimal. Extra burden is represented by the obtaining of the biopsy, which will be used to isolate cells for culture of the construct, the fact that the evaluation of the wounds will take more time at follow-up, and by the optional biopsies at 3 months follow-up. A possible risk will be intolerance or an allergic reaction to one of the skin-graft components. Other than these, no additional risks when compared to the standard treatment are envisioned. The rationale behind this treatment is that it will lead to improved scar quality with better cosmetic

and functional properties in time compared to conventional treatment. Taken together, to the best of our current knowledge, the estimated risk/benefit ratio is favourable.

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

- Age > 18 years and < 70 years
- Medical indication for reconstructive surgery in which a full thickness skin defect arises which otherwise would be closed with STSG
- Written informed consent by the patient

Exclusion criteria

When any of the following criteria are met, the potential subject will be excluded from participation in this study:
- Patients with infected wounds or positive general microbiological swabs taken from the nose for multi-resistant germs
- Patients tested positive for HBV, HCV, syphilis or HIV
- Patients with known underlying or concomitant medical conditions that may interfere with normal wound healing (e.g. immune deficiency, systemic skin diseases, any kind of congenital defect of metabolism including diabetes)
- Coagulation disorders as defined by INR outside its normal value, PTT >ULN and fibrinogen - Previous enrolment of the patient into the current study
- Participation of the patient in anotherinterventional study within 30 days preceding and during the present study
- Patients expected not to comply with the study protocol
- Suspicion of child abuse (for the study in Switzerland)
- Pregnant or breast feeding patients
- Contamination derived from biopsy which could interfere with patients health. The decision will be taken after discussion with the responsible physicians.
- Due to patient derived variations, isolated cells from biopsy do not proliferate or proliferate insufficiently
- Skin substitute has not been released due to production specific deviations
- Patients allergic to amphotericin B and gentamicin

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	8
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Generic name:	Somatic cells autologous

Ethics review

Approved WMO Date:	20-10-2015
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	20-04-2016
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	28-09-2017
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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
EudraCT	EUCTR2015-002725-19-NL
CCMO	NL53075.000.15