OTR4120: topical application to split-skin graft donor sites. A clinical evaluation on the healing.

Published: 17-04-2009
Last updated: 06-05-2024

Objective: To demonstrate the efficacy of a novel matrix therapy based technology that creates improved wound healing in a clinical donor site model.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Procedural related injuries and complications NEC
Study type	Interventional

Summary

ID

NL-OMON33585

Source
ToetsingOnline

Brief title
OTR4120 to skin-graft donor sites

Condition

- Procedural related injuries and complications NEC

Synonym
burn wounds, donor skin

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Nederlandse Brandwondenstichting

Intervention

Keyword: donor sites, OTR4120, wound healing

Outcome measures

Primary outcome

-Clinical improvement of the donor site wound, measured as reduction in wound size in time.

Secondary outcome

-Complete healing of the wound, measured as the time needed for complete healing.

-Improvement of the quality of the (former) wound area to be measured as the amount of vascularisation, skin pigmentation and elasticity.

-Pain reduction.

-Itch reduction.

Study description

Background summary

OTR4120 is a heparan sulfate mimetic that optimizes the regeneration of injured tissues by sequestering growth factors in the extracellular matrix. From multiple animal studies it is known that OTR4120 application to wounds improves tissue regeneration both in speed of healing and in improved tissue architecture.

Split-skin grafts change the matrix- en celular bed of the epidermis. Destruction of the cells and the matrix release enzymes who destroy the

glycosaminoglycans (GAG) and proteins, present in the extracellular matrix. The natural repair process of a wounds needs recovery of the matrix and the formation of novel matrix components. In addition, the replacement of dead cells by new cells is needed. This takes place from adjecent identical cell populations that multiply and migrate to the wound area. During wound repair this process is suboptimal, which hampers the influx of cells.

OTR4120 is a structural and functional analogue of GAG. From multiple animal studies it is known that OTR4120 application on wounds increases the speed of healing and tissue architecture of the regenerate. When applied to a wound area, OTR4120, like a GAG, bind to specific areas on the extracellular matrix where the GAG*s were degraded. By protecting matrix proteins from degradation, it stimulates cell attachement, cell migration and cell devision. This way OTR4120 will act as wound repair enhancer.

Study objective

Objective: To demonstrate the efficacy of a novel matrix therapy based technology that creates improved wound healing in a clinical donor site model.

Study design

Dubbel blinded, placebo controlled trial for 19 patients having a standardised split-skin graft donor site wound. This wound will be divided in 3 parts. The proximal and distal part will be treated, during 2 weeks, with OTR4120 or placebo. The middle part of the wound will be untreated. In addition, regular treatment will be given to these patients.

Intervention

Wetted compresses, soaked in OTR4120 or placebo, will be placed on parts of the wound during 5 minutes.

Study burden and risks

Burden: OTR4120 or placebo, on a wetted gauze, will be placed on the wound during 5 minutes followed by the standardized regular treatment.

Risks: no risks in the use of the dextranderivative OTR4120, used in a microgram range per treatment, are known or expected.

Contacts

Public

Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr Molewaterplein 50
3015 GD Rotterdam
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr Molewaterplein 50
3015 GD Rotterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Informed consent
2. Aged over 18 yrs
3. Patients in need of an autologous skin graft
4. Adequate nutritional state
5. Adequate immuno-competence
6. Women in reproductive age take contraceptive medication

Exclusion criteria

1- Minor patients
2- Pregnant or breastfeeding women
3- Patients unable to sign the informed consent
4- Uninsured patients

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2009
Enrollment:	19
Type:	Actual

Medical products/devices used

Generic name:	CACIPLIQ20
Registration:	Yes - CE outside intended use
Product type:	Medicine
Brand name:	Cacipliq20
Generic name:	OTR4120
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	17-04-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date:	20-04-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	EUCTR2009-010478-39-NL
CCMO	NL25119.078.09