Protocol for the clinical evaluation of wounds after topical administration of OTR4120 to ulcers.

Published: 21-12-2007
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To validate that OTR4120 will improve the healing of chronic ulcers.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Diabetic complications
Study type	Interventional

Summary

ID

NL-OMON35339

Source
ToetsingOnline

Brief title
OTR4120 application to ulcers.

Condition

- Diabetic complications
- Skin vascular abnormalities
- Vascular hypertensive disorders

Synonym
diabetic ulcers, venous ulcers

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Fonds NutsOhra; de firma OTR3;Parijs,OTR3, rue Francaise 4, 75001, Paris

Intervention

Keyword: OTR4120, PUSH tool, ulcers, wound healing

Outcome measures

Primary outcome

Clinical improvement of the ulcer, measured as reduction in wound size in

time.

Secondary outcome

1- Complete healing of the ulcer, measured as the time needed for complete

healing.

2- Pain reduction without the use of pain medication.

Study description

Background summary

Chronc ulcers display an increasing incidence due to our aging society and put a strong burden on the patients' quality of life.

Matrix and cellular characteristics are changed in skin ulcers ranging from dermis to muscle layer. Destruction of cells and matrix releases enzymes that attack the glycosaminoglycans (GAGs) and proteins in the extracellulair matrix. The natural proces of tissue repair requires matrix reconstitution and cellular replacement. If these processes are hampered, ulcers may become chronic.

OTR4120 is a structural and functional analogue of GAG. When applied to an ulcered area, it will bind to tissue parts where the natural GAGs are degraded. This way OTR4120 will act as a wound healing enhancer by protecting matrix-associated proteins from degradation and by enhancing cell migration into the wound area.

Study objective

To validate that OTR4120 will improve the healing of chronic ulcers.

Study design

Dubbel blinded, randomized, placebo controlled trial in 2 groups of 62 patients having chronic ulcers. Group 1 will be treated during 4 months using OTR4120. Group 2 will be placebo treated. In addition, both groups will receive their standardized regular treatment.

Intervention

Compress, soaked in OTR4120 or placebo, will be placed uopn the ulcer for a period of 5 min.

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 the microgram range per treatment, are known or expected.

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

1. Informed consent.
2. Aged over 18 yrs.
3. Patients displaying an ulcus cruris following PUSH tool criteria or diabetic foot ulcer.
4. Women in reproductive age take contraceptive medication.

Exclusion criteria

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

Study design

Design

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):	12-03-2008

Enrollment:	124
Type:	Actual

Medical products/devices used

Generic name:	OTR4120
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	21-12-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	27-06-2008
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	16-12-2008
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	25-05-2009
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	31-05-2010
Application type:	Amendment
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
CCMO	NL20585.078.07
Other	NTR1242 NTR1603