Double blind, placebo controlled study Tacrolimus versus Emmolient in localized scleroderma

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The primary objective of this study is to assess whether tacrolimus is effective for the treatment of morphea.

Ethical review	Approved WMO
Status	Pending
Health condition type	Connective tissue disorders (excl congenital)
Study type	Observational non invasive

Summary

ID

NL-OMON31329

Source
ToetsingOnline

Brief title
tacrolimus

Condition

- Connective tissue disorders (excl congenital)

Synonym
localized scleroderma, morphoea

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: de zalven zullen verstrekt worden door de afdeling Dermatologie in samenwerking met Astellas (farmaceut)

Intervention

Keyword: morphoea, placebo, tacrolimus 0.1%, therapeutic effect

Outcome measures

Primary outcome

Initial assessment includes complete skin examination, durometerscore, a MSS score, a histological investment of a representative sclerodermatous lesion (to confirm the diagnose). Clinical features as dyspigmentation, induration, atrofia, erythema and telangiectasia will be rated on a scale of 0 (none), 1 (mild), 2 (moderate) and 3 (severe). The lesions will also be photographed and measured during each visit. Adverse reactions will be assessed. A histological and a semi-quantitative (scale 0-6) clinical evaluation will be performed after 3 months.

Secondary outcome

Nvt

Study description

Background summary

Only case-reports showed that topical tacrolimus, an immunosuppressive macrolide antibiotic, is effective and well tolerated in patients with localized scleroderma.
However no double blind placebo controlled study is performed whether tacrolimus is an effective treatment for morphea.
Tacrolimus is a immunomodulatory drug that act predominantly on T-cells.

Study objective

The primary objective of this study is to assess whether tacrolimus is effective for the treatment of morphea.

Study design

All the patients with a localized scleroderma will be recruited from the outpatients clinic from the Dermatology Department of the Radboud University Hospital Nijmegen, the Netherlands.
20 patients will be selected with a localized scleroderma. This study will have a 3 month follow up.
All the patients will be treated with an emolient and with tacrolimus 0.1% (protopic®, Astellas) in a double blind selection on two selected morpheaplaques. The ointment will be applied twice daily. Wash out time for dermatocorticosteroids will be 3 weeks and for systemic immunosuppressives or antifibrotic therapy 3 months.
Protopic (a steroid free ointment) is a registrated and common used therapy for the treatment of eczema.

Study burden and risks

Protopic will be applied on small body surface. The side effects will be low.
No serious side effects are expected.
Tacrolimus is a registrated treatment for atopic dermatitis. The investigators have enough experience with this topical treament.
Burden: patients have to come 3 times extra to the hospital. Each visit will take approximately 20 minutes.
The studyparameters give minimal discomfort for the patient.

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

Adults (aged ³ 18 years)
Patients must have a clinical diagnose of active morphea
Patients must have stopped systemic immunosuppressives/antifibrotic agents 3 months before start of this study
Wash out time for local treatments (like dermatocorticosteroids) is 3 weeks

Exclusion criteria

Prooved adverse reactions of protopic (tacrolimus) in the past (hypersensitivity/intolerance)
Females who are pregnant or nursing or planning to become pregnant
Recent treatment with (dermato) corticosteroids or other antifibrotic therapy
Active skin infection at the morpheaplaque
Recent vaccination (from 14 days before start of this study)

Study design

Design

Study phase:	2
Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2007
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	emolliens, zoals cremor lanette I
Generic name:	cremor lanette I
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	protopic 0.1%
Generic name:	Tacrolimus ointment 0.1%
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	03-09-2007
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	EUCTR2007-004796-19-NL
CCMO	NL19464.091.07