

# Is Medical Moisture Retention Creme more effective than cetomacrogol creme FNA for treatment of venous eczema? A single blinded, randomised controlled study in the wound treatment centers in the Netherlands

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Studying whether the effectiveness of Medical Moisture Retention Cream (Alhydran®) is greater than that of Cetomacrogolcrème FNA on duration healing of matig ernstig venous eczema, as well as reduction of the complaints associated with venous eczema...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Epidermal and dermal conditions
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON46387

### Source

ToetsingOnline

### Brief title

MMRC-CETO trial

### Condition

- Epidermal and dermal conditions

### Synonym

Hypostatic eczema

### Research involving

Human

## Sponsors and support

**Primary sponsor:** BAP medical-medical care for the skin

**Source(s) of monetary or material Support:** Alleen BAP medical financiert het onderzoek

## Intervention

**Keyword:** eczema, treatment, venous insufficiency

## Outcome measures

### Primary outcome

Primary outcome measure: percentage of patients with eczema healed in a 6-week period.

### Secondary outcome

Secondary Objective (s):

1. Percentage of patients with a reduction in the severity of the eczema.
2. Time to cure
3. Percentage of patients who have reduced the severity of itching symptoms, measured with the VAS scale.
4. The number of patients who decided to prescribe local corticosteroids in the course of the study (= end of study participation).

## Study description

### Background summary

Venous eczema often develops in the presence of a venous venousleg ulcer, and leads to an unpleasant erythematous, spontaneously moisturizing, scaly and itchy skin.

An adequate and professionally responsible analysis of the existing venous ulcer is beneficial for the treatment of the ulcer. However, optimal wound

treatment goes further and also focuses on the assessment of the skin around the ulcer, the so-called periwound skin.

A healthy epidermis (stratum corneum) provides an effective permeability barrier that prevents water from being lost and the penetration of harmful irritants and potential allergens is prevented. For this, patients with dry skin, but also those with normal healthy skin, often use moisturizers. Studies show that some moisturizers weaken the barrier of the skin, while others strengthen it.

Medical Moisture Retention Cream (Alhydran®) is an oil in water emulsion that incorporates fresh pure Aloe Vera and other greasy ingredients. The mechanism of action of MMRC involves the moisturizing effect of the Aloe Vera gel, in combination with the moderate sealing nature of the greasy ingredients of the moisturizing cream. The balanced degree of occlusion of the skin in combination with the hydrating effect of MMRC brings the Trans Epidermal Water loss (TEWL) to values \*\*close to that of normal skin.

Cetomacrogol cream FNA is a hydrophilic cream that cares for the skin and prevents dehydration. It contains cetomacrogol wax, decylolate, sorbic acid, sorbitol and water. The cream quickly absorbs into the skin after application and softens and protects the irritated skin. Cetomacrogol cream is often used as a base and to support the treatment of various skin conditions, such as eczema and itching.

Pilot research has shown that Medical Moisture Retention cream symptoms are illuminated faster than the standard treatment in accordance with NHG standard with cetomacrogol.

## **Study objective**

Studying whether the effectiveness of Medical Moisture Retention Cream (Alhydran®) is greater than that of Cetomacrogolcrème FNA on duration healing of matig ernstig venous eczema, as well as reduction of the complaints associated with venous eczema

## **Study design**

After randomization, patients are prosecuted for 6 weeks. patients are from primary care, referred by the GP to 1 of the 3 wound treatment centers. Only competent patients are included after informed consent. Patients can stop participating without giving any reason.

Scedule RCT

Diagnoses venous eczema

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Check inclusion/exclusion criteria

\*

Permission for participation, oral and scriptural

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Signed Informed Consent

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Randomisation

\* \*

Basis data Basis data

\* \*

Kind of compression Kind of compressione

\* \*

Start zero measurement Start zero measurement

\* \*

Visit week 1 Visit week 1

\* \*

Visitweek 3 Visit week 3

\* \*

End visit week 6 End visit week 6

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Analysis data

## **Intervention**

Cetomacrogol creme versus MMRC

## **Study burden and risks**

Necessary examinations and anamnesis are part of standard research in patients with venous eczema, so not burdensome.

A method of ambulatory compression has been chosen, which is easier and faster to apply than the guideline treatment with short stretch bandages. Except for taking extra written information there is no extra tax.

Normally, more patients with venous eczema would be treated with cr. cetomacrogol FNA, so the control group does not receive any extra risk. The intervention group is treated with Medical Moisture Retention Cream, of which rarely local reactions have been reported, so this leads to a low risk

## **Contacts**

### **Public**

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### **Scientific**

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

### **Inclusion criteria**

Patient older than 18 years

Patient with venous eczema and venous leg ulcer

Severity eczema mild-POEM score 8-16

2 treatments a day possible

signed informed consent

### **Exclusion criteria**

allergic for MMRC or cetomacrogol

other type of eczema

treated in the last 4 weeks with one of the study cream or a corticosteroid cream

EAI<0.8 and toe pressure<75 mm Hg

Treated diabetes mellitus

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	02-04-2018
Enrollment:	180
Type:	Anticipated

### Medical products/devices used

Generic name:	CR Cetomacrogol FNA and Medical Moisture Retension Creme
Registration:	Yes - CE intended use

## Ethics review

Approved WMO	
Date:	02-05-2018
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

## 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	NL64630.028.18