

# Standard Treatment Or topical doxepin against Pruritus in burn patients.

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON25795

### Source

Nationaal Trial Register

### Brief title

STOP trial

### Health condition

pruritus, jeuk  
burns, brandwonden

## Sponsors and support

**Primary sponsor:** Association of Dutch Burn Centres

**Source(s) of monetary or material Support:** Dutch burns foundation

## Intervention

## Outcome measures

### Primary outcome

To evaluate whether doxepin hydrochloride 5% cream is more effective in reducing pruritus in patients with burns than standard treatment.

### Secondary outcome

To evaluate whether patients treated with doxepin hydrochloride 5% cream compared to standard treatment:

1. Have a better quality of life;
2. Have less erythematous scars.

## Study description

### Background summary

Pruritus is a common problem in patients with healed burn wounds and causes severe morbidity. Standard treatment of pruritus consist of moisturizers, pressure garments and oral antihistamines. Doxepin hydrochloride 5% cream has potent H1 and H2 histamine receptor blocking properties and was found to have anti-pruritic properties in previous studies in patients with burns.

Our goal is to perform a randomised, double-blind study to evaluate the efficacy of doxepin hydrochloride 5% cream.

### Study objective

Doxepin cream is more effective in reducing postburn pruritus compared with standard treatment.

### Study design

During the first two weeks patients will keep a diary. Furthermore patients will visit the out-patient clinic at randomisation (0 weeks), 2 weeks, 6 weeks and 12 weeks for additional assessments.

### Intervention

Patients will be randomised between:

1. Doxepin hydrochloride 5% cream, placebo tablets;
2. Placebo cream, clemastine 1 mg tablets.

Treatment will be given as long as the complaints persist.

## Contacts

### Public

Association of Dutch Burn Centres<br>  
Burn Center Martini Hospital<br>  
Van Swietenplein 1  
H.C. Kuipers  
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The Netherlands  
+31 (0)50 5245565

### Scientific

Association of Dutch Burn Centres<br>  
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## Eligibility criteria

### Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

1. Patients with healed burns and itch;
2. Itch intensity as assessed by VAS score greater than or equal to 3;
3. Patients treated in one of the three Dutch burn centres;
4. Patients aged 18 years or older.

### Exclusion criteria

An eligible subject who meets any of the following criteria will be excluded from participation in this study:

1. Inability to give informed consent by patient or legal representatives;
2. Inability to understand and fill in VAS scores and quality of life/pruritus assessment

questionnaires, as judged by the treating physician;

3. Known pregnancy or breast-feeding;

4. (Active) cutaneous or systemic disease causing itch;

5. Any disease or condition which, according to the physician's judgement, is associated with adverse effects using doxepin.

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	27-12-2013
Enrollment:	108
Type:	Anticipated

## Ethics review

Positive opinion	
Date:	06-03-2013
Application type:	First submission

## Study registrations

## Followed up by the following (possibly more current) registration

ID: 39365

Bron: ToetsingOnline

Titel:

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

Register	ID
NTR-new	NL3720
NTR-old	NTR3883
CCMO	NL40807.094.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON39365

## Study results

### Summary results

1. Demling R, DeSanti L, Nelson R. Pruritus and burn wound. Wounds 2002;14:2A-7A. <br>
2. Demling R, DeSanti L. Topical doxepin significantly decreases itching and erythema in the chronically pruritic burn scar. Wounds 2003;15(6):195-200.