

# Treatment of itch with naltrexone in patients with burns: an explorative, randomised, double blind, placebo-controlled, cross-over clinical trial

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON31113

### Source

ToetsingOnline

### Brief title

Burns Itch TreatmEnt Study (BITE)

### Condition

- Other condition
- Epidermal and dermal conditions

### Synonym

itch, pruritus

### Health condition

jeuk bij patienten met brandwonden

## Research involving

Human

## Sponsors and support

**Primary sponsor:** Martini Ziekenhuis

**Source(s) of monetary or material Support:** Vereniging Samenwerkende Brandwondencentra Nederland (VSBN)

## Intervention

**Keyword:** Burns, Naltrexone, Pruritus, Treatment

## Outcome measures

### Primary outcome

Mean itch intensity score at end point, defined as the mean of the last 7 diary entries while the patient is receiving study medication.

The percentage change in itch intensity score from baseline is calculated as:

$1 - (\text{mean itch intensity score end point} / \text{mean itch intensity score baseline})$

$\times 100\%$

### Secondary outcome

Additional aspects of itch (e.g. frequency, duration), the effect of treatment as perceived by the patient, pain, and various aspects of anxiety and sleep.

## Study description

### Background summary

It is clinically well known that itch (pruritus) is one of the most disturbing physical complaints in persons with burns. Like in many inflammatory skin diseases, itch has been shown to affect the quality of life of persons with burns in aspects such as sleep disturbances, impairments of daily activities, and psychosocial well-being. Despite these reports and the urgent clinical need to relieve the suffering from itch, it is still one of the unresolved scar-related problems in burn care practice.

Most patients with burn wounds develop itch which can last for several months to years. The current standard approach with vaseline, pressure clothing and occasionally anti-histamine is often ineffective and currently no other medicine have proven to be effective. As possible treatment of itch, we want to investigate the effectiveness of naltrexone. Via opioid receptors in the central and peripheral nervous system endogenous opioids are modifying the perception of itch. The opioid antagonist naltrexone of the  $\mu$ -,  $\kappa$ -, and  $\delta$  receptors will suppress the opioid pathway and could therefore be effective in the treatment of itch in patients with burn wounds. Naltrexone has already been used with success in cholestatic pruritus and different dermatological forms of pruritus.

## **Study objective**

The primary objective of this study is to evaluate the efficacy and safety of naltrexone in the treatment of itch in patients with burn wounds. The nature of the association(s) of the - reduction of the - intensity of itch with sleep and anxiety in particular will also be analysed.

## **Study design**

This study concerns an explorative, randomised, double blind, placebo-controlled, cross-over clinical trial. In total 20 patients will be included.

## **Intervention**

Patients will take either naltrexone or placebo for two weeks and are randomised to start with one or the other. Before the 2 treatment periods a baseline measurement of 7 days will be done. In between the two treatment periods there will be a wash-out period of 3 days. The naltrexone dose will be 50mg once daily. On the first day patients will receive two times 25mg of naltrexone with at least one hour in between.

## **Study burden and risks**

Side-effects may occur when taking naltrexone, these are mostly mild and transient. Furthermore, patients are asked to fill out a trial diary on a daily basis and a blood sample is taken once. In total, patients have to come to the hospital 3 times because of their participation in this trial. However, every effort will be made to let these visits coincide with their regular clinical follow-up visits.

Till now there is no effective treatment of itch in patients with burn wounds. Many studies with significant declines in itch scores have been performed with naltrexone for treatment of different origins of pruritus (e.g. cholestatic and dermatological pruritus) with minor side effects.

There have not been any studies of naltrexone treatment in patients with burn wounds and itch. Naltrexone seems a promising drug for the treatment of itch in patients with burn wounds. When naltrexone is effective it can be used worldwide in patients with burn wounds to treat itch.

## 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

Eligible for inclusion are patients with (almost) healed burns who have been admitted to the burn centre , and are 18 years of age or older with itch 4-6 weeks postburn.

## Exclusion criteria

Patients will be excluded when meeting one of the following exclusion criteria:

- TBSA of more than 20%
- liver insufficiency (in this study that means more than 2 times the normal range of the liverenzymes: ASAT> 80 U/L and/or ALAT >80 U/L and/or AF > 250U/L and/or gamma GT >100U/L)
- acute hepatitis
- history of drug/alcohol abuse
- known sensitivity for any of the following substances: naltrexonehydrochloride, lactose monohydrate, crospovidone, powder cellulose, microcrystalline cellulose, colloid silicon dioxide, magnesium stearate, hypromellose, macrogole 4000, Titanium dioxide (E171), Black iron oxide (E172), Red iron oxide (E172), Yellow iron oxide (E172), carboxymethylamylum sodium type A, precirrole.
- pregnant
- breast feeding
- having used opioids 10 days prior to the start of treatment
- using itch medication other than the study medication and unwilling to stop
- psychiatric disorder
- other disease associated with itch (eg excema, atopic dermatitis, cholestatic pruritus)
- insufficiently proficient in Dutch to give informed consent and/or fill out the questionnaires

## Study design

### Design

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

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-08-2007
Enrollment:	20

Type: Anticipated

## Medical products/devices used

Product type: Medicine  
Brand name: Naltrexonehydrochloride 50 PCH  
Generic name: Naltrexone  
Registration: Yes - NL outside intended use

## Ethics review

Approved WMO  
Date: 04-07-2007  
Application type: First submission  
Review commission: BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

## 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	EUCTR2007-002638-12-NL
CCMO	NL17849.056.07