# Treatment of itch with naltrexon in patients with burns

Submission date	Recruitment status	[X] Prospectively registered
23/08/2007	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
23/08/2007	Completed	Results
Last Edited	Condition category	Individual participant data
04/12/2007	Injury, Occupational Diseases, Poisoning	Record updated in last year

#### Plain English summary of protocol

Not provided at time of registration

# Contact information

#### Type(s)

Scientific

#### Contact name

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## Additional identifiers

#### Protocol serial number

N/A

# Study information

#### Scientific Title

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

#### **Acronym**

BITE (Burns Itch TreatmEnt study)

#### **Study objectives**

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.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Ethics approval received from the local ethics board (Stichting Beoordeling Ethiek Biomedisch Onderzoek, Medisch Ethische toetsingscommissie [METC Assen]) on the 4th July 2007 (ref: MZH 2007-20).

#### Study design

Randomised, double-blind, placebo controlled, crossover group trial

#### Primary study design

Interventional

#### Study type(s)

Treatment

#### Health condition(s) or problem(s) studied

Burns

#### Interventions

Patients will take either naltrexone or placebo for two weeks and are randomised to start with one or the other. Before the two 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 50 mg once daily. On the first day patients will receive two times 25 mg of naltrexone with at least one hour in between. The procedure on the first day will be mimicked where the placebo is concerned.

#### Intervention Type

Other

#### Phase

**Not Specified** 

#### Primary outcome(s)

- 1. Mean itch intensity score at endpoint, 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 (mean itch intensity score end point/mean itch intensity score baseline) x 100%

# Key secondary outcome(s))

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

#### sleep:

- 2.1. Itch presence, measured at baseline 1
- 2.2. Demographics, measured at baseline 1
- 2.3. Burn injury characteristics, measured at baseline 1
- 2.4. Polymorphism  $\mu$ -receptor (DNA), measured at intervention week 2
- 2.5. Blood plasma level, measured at intervention week 2 and intervention week 4
- 2.6. Scar:
- 2.6.1. Patient and Observer Scar Assessment Scale (POSAS), measured at baseline 1 and intervention week 4
- 2.6.2. Dermaspect, measured at baseline 1 and intervention week 4
- 2.7. Itch:
- 2.7.1. Visual Analogue Scale (VAS) measured daily throughout treatment
- 2.7.2. Body-Image Ideals Questionnaire (BIQ), measured at baseline 1, intervention week 1, intervention week 2, baseline 2, intervention week 3, intervention week 4 2.8. Sleep:
- 2.8.1. Visual Analogue Scale (VAS) measured daily throughout treatment
- 2.8.2. Medical Outcomes Study (MOS)-Sleep, measured at baseline 1, intervention week 1, baseline 2, intervention week 3
- 2.9. Pain: Visual Analogue Scale (VAS) measured daily throughout treatment
- 2.10. Anxiety: Hamilton Anxiety and Depression Scale (HADS), measured at baseline 1, intervention week 1, baseline 2, intervention week 3
- 2.11. Treatment effect: Patient Global Impression of Change (PGIC), measured at intervention 2 and intervention 4
- 2.12. Adverse Drug Reaction, measured daily during the intervention and wash out periods

#### Timepoints:

Baseline 1: 7 days

Intervention week 1: 7 days Intervention week 2: 7 days

Wash-out 1: three days

Baseline 2: 7 days

Intervention week 3: 7 days Intervention week 4: 7 days

Wash-out 2: 3 days

#### Completion date

01/07/2008

# **Eligibility**

#### Key inclusion criteria

Eligible for inclusion are patients:

- 1. With (almost) healed burns who have been admitted to the burn centre
- 2. Who are 18 years of age or older with itch 4 6 weeks post burn

#### Participant type(s)

Patient

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Sex

Not Specified

#### Key exclusion criteria

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

- 1. Total Body Surface Area (TBSA) of more than 20%
- 2. Liver insufficiency (in this study that means more than two times the normal range of the liver enzymes: Aspartate Aminotransferase [ASAT] greater than 80 U/L and/or Alanine Aminotransferase [ALAT] greater than 80 U/L and/or Alkaline Phosphatase [AP] greater than 250U/L and/or Gamma Glutamyl Transpeptidase [GGT] greater than 100U/L)
- 3. Acute hepatitis
- 4. History of drug/alcohol abuse
- 5. 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, precirole
- 6. Pregnant
- 7. Breast feeding
- 8. Having used opioids 10 days prior to the start of treatment
- 9. Using itch medication other than the study medication and unwilling to stop
- 10. Psychiatric disorder
- 11. Other disease associated with itch (e.g. eczema, atopic dermatitis, cholestatic pruritus)
- 12. Insufficiently proficient in Dutch to give informed consent and/or fill out the questionnaires

#### Date of first enrolment

01/09/2007

#### Date of final enrolment

01/07/2008

# Locations

#### Countries of recruitment

Netherlands

#### Study participating centre Martini Hospital

Groningen Netherlands 9700 RM

# Sponsor information

## Organisation

Martini Hospital (The Netherlands)

#### **ROR**

https://ror.org/017b69w10

# Funder(s)

## Funder type

Research organisation

#### **Funder Name**

Association of Dutch Burn Centres (ADBC) (The Netherlands)

# **Results and Publications**

Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration