Treatment of itch with naltrexon in patients with burns

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27783

Source
Nationaal Trial Register

Brief title
BITE (Burns Itch TreatmEnt study)

Health condition

Pruritus, Burns, Naltrexone, Treatment

Jeuk, Brandwonden, Naltrexon, Behandeling

Sponsors and support

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Source(s) of monetary or material Support: Association of Dutch Burn Centres (ADBC)

Intervention

Outcome measures

Primary outcome

1. Mean itch intensity score at end point, defined as the mean of the last 7 diary entries while the patient is receiving study medication.
2. 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%

Secondary outcome

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.

Study description

Background summary

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, naltrexone is investigated. Via opioid receptors in the central and peripheral nervous system endogen opioids modify the perception of itch. The opioid antagonist naltrexone of the ì-, ê-, en ä receptors suppresses the opioid pathway and could therefore be effective in the treatment of itch in patients with burn wounds.

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.

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. The procedure on the first day will be

mimicked where the placebo is concerned.

Contacts

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Eligibility criteria

Inclusion criteria

Eligible for inclusion are patients:
1. with (almost) healed burns who have been admitted to the burn centre;
2. 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:
1. TBSA of more than 20%;
2. 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);
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 (eg excema, atopic dermatitis, cholestatic pruritus);
12. Insufficiently proficient in Dutch to give informed consent and/or fill out the questionnaires

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2007
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	31-07-2007
Application type:	First submission

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
NTR-new	NL1001
NTR-old	NTR1030
Other	:
ISRCTN	ISRCTN68179235

Study results