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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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
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%

Secondary outcome measures
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 μ-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

Overall study start date
01/09/2007

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

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
20

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

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/017b69w10

Funder(s)

Funder type
Research organisation

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

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration