Behandeling van jeukklachten bij brandwondpatiënten met doxepine crème

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25977

Source
Nationaal Trial Register

Brief title
2-STOP

Health condition

Itch, burns, jeuk, brandwonden

Sponsors and support

Primary sponsor: Prof. E. Middelkoop, PhD
Association of Dutch Burn Centres
Zeestraat 27-29, 1941 AJ Beverwijk
Source(s) of monetary or material Support: Dutch Burn Foundation

Intervention

Outcome measures

Primary outcome

The main study parameter is the change in pruritus intensity as measured by the Visual

Analogue Scale (VAS), with a decrease of ≥2 point being defined as clinically significant.

Secondary outcome

The secondary study parameters include the determination of the MIC of the itch scores, the characteristics and impact of itch as measured by the BIQ, and scar quality as measured by the POSAS.

Other study parameters include: the use of hydrating cream, use of escape medication and use of pressure garments. Furthermore, we will register sex, age, medical history, cause of burn, location of burn wound, %TBSA burned, time to wound healing (will be estimated retrospectively), % burn wound area that itches, duration of itch, itch before inclusion and wound treatment (conservative or surgery).

Study description

Background summary

This is a multicentre, double-blind, randomized, placebo-controlled cross-over trial to investigate whether the use of doxepin cream versus a placebo cream significantly reduces itch by comparing itch scores in patients with healed burns.

Study objective

Doxepin hydrochloride 5% cream significantly reduces pruritus in burn patients in comparison with a placebo cream

Study design

Timepoint 0: baseline data, burns itch questionnaire and POSAS.

Daily 1-14: VAS (itch score), side effects, use of other medication, use of escape moisturizer, use of pressure garments.

Day 14: burns itch questionnaire

Daily 22-35: VAS (itch score), side effects, use of other medication, use of escape moisturizer, use of pressure garments.

At 5-6 weeks: burns itch questionnaire

Intervention

Patients will be randomized to start with either the doxepin cream or the placebo cream. Patients will be required to use the cream at least once daily for two consecutive weeks. This is followed by a one week wash-out period after which they continue with the other cream at least once daily for another two weeks.

Contacts

Public
Kelly Kwa
Vondellaan 13

Beverwijk 1942 LE
The Netherlands
0251-265741
Scientific
Kelly Kwa
Vondellaan 13

Beverwijk 1942 LE
The Netherlands
0251-265741

Eligibility criteria

Inclusion criteria

- Age ≥ 18 years

- Healed burns

- Itch with an intensity ≥ 3 as determined by the VAS score for itch at time of the enrolment

- Treatment in one of the three Dutch burn centres

- Total area that itches must not exceed >10% TBSA

Exclusion criteria

- Unable to give informed consent

- Unable to understand and fill in VAS scores and questionnaires (as determined by the treating burn physician)

- Cutaneous or systemic disease causing itch

- Any diseases or condition that is associated with adverse effects using doxepin, that is: Hypersensitivity to any of its components, Glaucoma, A tendency to urinary retention, Sever liver disease, Mania, Sever heart disease (including cardiac arrhythmias), Pregnancy and lactation

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2017
Enrollment:	27
Type:	Actual

Ethics review

Positive opinion

Date:	03-03-2017
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	NL6233
NTR-old	NTR6413
Other	EudraCT number, METC-number : 2016-003862-25, NL59341.0.94.16

Study results