Standard Treatment Or topical doxepin against Pruritus in burn patients

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To evaluate whether doxepin hydrochloride 5% cream is more effective in reducing pruritus in burn patients than standard treatment (clemastine).

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Epidermal and dermal conditions
Study type	Interventional

Summary

ID

NL-OMON39365

Source
ToetsingOnline

Brief title
STOP trial

Condition

- Epidermal and dermal conditions

Synonym
itch, pruritus

Research involving
Human

Sponsors and support

Primary sponsor: Vereniging Samenwerkende Brandwondencentra Nederland
Source(s) of monetary or material Support: Nederlandse Brandwonden Stichting

Intervention

Keyword: burns, doxepin, pruritus

Outcome measures

Primary outcome

The main study parameters are change in mean pruritus intensity; VAS scores from baseline during 12 weeks of treatment.

Secondary outcome

Secondary study parameters include quality of life as measured by the SF-36 questionnaire, characteristics of the itch as measured by the Burn Itch Questionnaire, reported somnolence and response of erythema.

Other study parameters include use of escape moisturizer and use of pressure garments. Furthermore age, gender, location of burn wound, post-burn period, total body surface area, size of itching area, length of period of itch, treatment before inclusion (if applicable) will be recorded.

Study description

Background summary

Pruritus is a common problem in 40-87% of patients with healed burn wounds. Chronically pruritic wounds affect quality of life and can inhibit healing due to recurrent scratching. Histamine is believed to be an important chemical mediator in the pathogenesis of pruritus associated with skin disorders. Histamine release also causes increased surface blood flow, which can lead tot a red skin surface. Standard treatment of pruritus involves oral administration of antihistamins, moisturizer and pressure garments, but this treatment fails in a great part of chronically itching burn patients. Little evidence is available on the treatment of post-burn pruritus, and a review has stressed the need for prospective, randomized controlled trials.
As regards to the agents with a peripheral action on the pruritic pathway, Doxepin shows great potential in burns literature because of the effectiveness and few adverse effects. Two studies have been published on the use of doxepin hydrochloride 5% cream in burn patients by Demling and DeSanti [Demling 2002 and Demling 2003]. These studies showed a significantly superior effect of doxepin hydrochloride 5% cream against pruritus compared to standard treatment

in burn patients. Proof of efficacy is limited as high quality randomized trials have not been performed.

Study objective

To evaluate whether doxepin hydrochloride 5% cream is more effective in reducing pruritus in burn patients than standard treatment (clemastine).

Study design

The study will be a multi-centre double-blind randomized -controlled trial.

Intervention

Patients will be randomized between:
1) Doxepin cream + placebo tablet or
2) Neutral cream + oral selective antihistamine (clemastine)

Patients are allowed to use pressure garnments and escape moisturizer if needed.

Study burden and risks

Patients will visit the out-patient clinic at randomization (0 weeks), 2 weeks, 6 weeks and 12 weeks. During these visits assesment of erythema will take place. Assesments are scheduled during regular follow-up and are non invasive. Quality of life and quality of itch questionnaires will be filled in at baseline and at 12 weeks. Completing these questionnaire will take approximately fifteen minutes. VAS scores for pruritus, experienced somnolence, used studymedication, hydrating cream and pressure garnments will be recorded daily during the first 2 weeks, at 6 weeks and at 12 weeks. This takes a few minutes each time.

Patients with burns who enter the study have a potential benefit of a marked reduction in pruritus by receiving doxepin cream 5% instead of standard treatment. They may however, suffer from some stinging and somnolence during the first couple of days. The effect of alcohol can be potentiated. Reported risks for doxepin hydrochloride 5% cream include development of allergic contact dermatitis and toxicity in case of topical overdose. Systemic effects which have been observed with orally administered doxepin hydrochloride are rarely observed with topical Xepin. These may include anticholinergic effects (dry mouth, changes in taste, dry eyes, blurred vision, urinary retention); central nervous system effects other than drowsiness (headaches, fever, dizziness); and gastrointestinal effects (nausea, indigestion, vomiting and diarrhoea or constipation).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Patients with healed burns and itch. Patients are divided into four groups i.e.
1) patients with partial thickness wounds, not exceeding 4 months postburn
2) patients with full thickness wounds, not exceeding 4 months postburn
3) patients with partial thickness wounds between 4 months postburn and 3 years postburn
4) patients with full thickness wounds between 4 months postburn and 3 years postburn
• Itch intensity as assessed by VAS score greater than or equal to 3
• Patients treated in one of the three Dutch burn centres
• Patients aged 18 years or older

Exclusion criteria

- Inability to give informed consent by patient or legal representatives
- Inability to understand and fill in VAS scores and quality of life/pruritus assessment questionnaires, as judged by the treating physician
- (Active) cutaneous or systemic disease causing itch
- Any disease or condition which is associated with adverse effects using doxepin, that is:
Contra-indications Tavegil
- hypersensitivity to clemastine or other arylalkylamine antihistamines, or any of the excipients
- porphyria
Precautions Tavegil:
- fructose intolerance
- narrow-angle glaucoma
- stenosing peptic ulcer
- pyloroduodenal obstruction
- prostatic hypertrophy with urinary retention and bladder neck obstruction
- galactose intolerance, Lapp lactose deficiency or glucose-galactose malabsorption
- pregnancy and lactation
Contra-indications Xepin:
- hypersensitivity to any of its components.
Precautions Xepin
- glaucoma
- a tendency to urinary retention
- severe liver disease
- mania
- severe heart disease (including cardiac arrythmias)
- pregnancy and lactation

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-12-2013
Enrollment:	108
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Tavegil
Generic name:	clemastine
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Xepin
Generic name:	doxepin hydrochloride 5%

Ethics review

Approved WMO Date:	22-07-2013
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)
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Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 25795
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2009-015090-12-NL
CCMO	NL40807.094.13
OMON	NL-OMON25795