

Standard Treatment Or topical doxepin against Pruritus in burn patients.

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Doxepin cream is more effective in reducing postburn pruritus compared with standard treatment.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25795

Bron

Nationaal Trial Register

Verkorte titel

STOP trial

Aandoening

pruritus, jeuk
burns, brandwonden

Ondersteuning

Primaire sponsor: Association of Dutch Burn Centres

Overige ondersteuning: Dutch burns foundation

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To evaluate whether doxepin hydrochloride 5% cream is more effective in reducing pruritus in patients with burns than standard treatment.

Toelichting onderzoek

Achtergrond van het onderzoek

Pruritus is a common problem in patients with healed burn wounds and causes severe morbidity. Standard treatment of pruritus consist of moisturizers, pressure garments and oral antihistamines. Doxepin hydrochloride 5% cream has potent H1 and H2 histamine receptor blocking properties and was found to have anti-pruritic properties in previous studies in patients with burns.

Our goal is to perform a randomised, double-blind study to evaluate the efficacy of doxepin hydrochloride 5% cream.

Doel van het onderzoek

Doxepin cream is more effective in reducing postburn pruritus compared with standard treatment.

Onderzoeksopzet

During the first two weeks patients will keep a diary. Furthermore patients will visit the out-patient clinic at randomisation (0 weeks), 2 weeks, 6 weeks and 12 weeks for additional assessments.

Onderzoeksproduct en/of interventie

Patients will be randomised between:

1. Doxepin hydrochloride 5% cream, placebo tablets;
2. Placebo cream, clemastine 1 mg tablets.

Treatment will be given as long as the complaints persist.

Contactpersonen

Publiek

Association of Dutch Burn Centres

Burn Center Martini Hospital

Van Swietenplein 1
H.C. Kuipers

Groningen 9728 NT
The Netherlands
+31 (0)50 5245565

Wetenschappelijk

Association of Dutch Burn Centres

Burn Center Martini Hospital

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Groningen 9728 NT
The Netherlands
+31 (0)50 5245565

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

1. Patients with healed burns and itch;
2. Itch intensity as assessed by VAS score greater than or equal to 3;
3. Patients treated in one of the three Dutch burn centres;
4. Patients aged 18 years or older.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

An eligible subject who meets any of the following criteria will be excluded from participation in this study:

1. Inability to give informed consent by patient or legal representatives;
2. Inability to understand and fill in VAS scores and quality of life/pruritus assessment questionnaires, as judged by the treating physician;
3. Known pregnancy or breast-feeding;

4. (Active) cutaneous or systemic disease causing itch;

5. Any disease or condition which, according to the physician's judgement, is associated with adverse effects using doxepin.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Dubbelblind
Controle:	Actieve controle groep

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	27-12-2013
Aantal proefpersonen:	108
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	06-03-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 39365
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3720
NTR-old	NTR3883
CCMO	NL40807.094.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON39365

Resultaten

Samenvatting resultaten

1. Demling R, DeSanti L, Nelson R. Pruritus and burn wound. Wounds 2002;14:2A-7A.

2. Demling R, DeSanti L. Topical doxepin significantly decreases itching and erythema in the chronically pruritic burn scar. Wounds 2003;15(6):195-200.