Amlexanox oral adhesive pellicles treats MiRAU.

Gepubliceerd: 17-03-2009 Laatst bijgewerkt: 18-08-2022

Amlexanox is not available in China yet or has not been generally accepted in clinical treatment. To explore the effectiveness of amlexanox oral adhesive pellicles in the treatment of minor recurrent aphthous ulcers.

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

Samenvatting

ID

NL-OMON22280

Bron
NTR

Verkorte titel
AOAP

Aandoening

HEALTH

Ondersteuning

Primaire sponsor: Beijing Fu Rei Kang Zheng Medical and Pharmaceutical Institute
Overige ondersteuning: 10th 5-Year Plan of National Key Technologies R&D Program in China (No.2004BA720A28), New Century Talents Support Program of MOE (NCET-04-0865).

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Amlexanox oral adhesive pellicles significantly reduced ulcer size and alleviated ulcer pain.

Toelichting onderzoek

Achtergrond van het onderzoek

Amlexanox has been developed as a 5% topical oral paste for the treatment of patients with RAS in most European countries. However, it is not available in China yet or has not been generally accepted in clinical treatment. To explore the effectiveness and safety of amlexanox oral adhesive pellicles in the treatment of minor recurrent aphthous ulcers, a randomized, blinded, placebo controlled, parallel, multicenter clinical study was designed. A total of 216 patients with MiRAU were recruited randomized to amlexanox or vehicle pellicles group. All patients were instructed to apply one pellicle to that identified ulcer 4 times a day (after meals and before bedtime) for 5 days (day 1 to day 5). The size and pain level of ulcers were measured and recorded on treatment days 0, 4 and 6. After five days treatment, amlexanox oral adhesive pellicles significantly reduced ulcer size and alleviated ulcer pain. None of the patients in the study was observed or reported to have any adverse experience. None of the hematologic values were considered clinically abnormal. There were also no laboratory differences between the 2 groups at baseline or day 6, and there were no significant changes over time.

Doel van het onderzoek

Amlexanox is not available in China yet or has not been generally accepted in clinical treatment. To explore the effectiveness of amlexanox oral adhesive pellicles in the treatment of minor recurrent aphthous ulcers.

Onderzoeksopzet

Five days.

Onderzoeksproduct en/of interventie

Subjects were instructed to apply 1 pellicle to that identified ulcer 4 times a day for 5 days.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Males and females aged 18-60 years old;

2. Willingness to participate and sign the informed consent forms;

3. Presenting with 1 to 5 aphthous ulcers (less than 72 hours duration) with a size no greater than 5 mm in diameter;

4. An expectation that their ulcers normally take 5 or more days to resolve without treatment;

5. Normal sense of pain, without anesthesia or paresthesia.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. A known history of serious drug hypersensitivities;

2. Pregnancy and lactation (Urine hCG-positive);

3. Concurrent clinical conditions that could pose a health risk to the subjects, including serious liver, kidney, and heart dysfunctions;

4. A history of an immunologic problem;

5. Ulcers as a manifestation of a systemic disease process such as ulcerative colitis, Crohns disease, Behcet¡s syndrome, or serious anemia;

6. Treatment with systemic steroid or other immunomodulatory agents within 1 month before the study entry;

7. Use of nonsteroidal anti-inflamatory drugs or oral antihistamines within 1 month prior to the study entry;

8. Treatment of the ulcer with any preparation or medication within 72 hours prior to the study entry;

9. Treatment with systemic antibiotics within 2 weeks prior to the study entry;

10. Attendance of any other clinical trials within 3 months prior to the study entry.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	31-03-2005
Aantal proefpersonen:	216
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	17-03-2009

Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1630
NTR-old	NTR1727
Ander register	: N/A
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A