Reduction of adverse effects by systemic antihistamines during therapy with fumarates in severe chronic plaque psoriasis.

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N/A

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

Samenvatting

ID

NL-OMON20745

Bron
NTR

Verkorte titel
N/A

Aandoening

Psoriasis vulgaris

Ondersteuning

Primaire sponsor: Erasmus Medical Center Rotterdam, Departement of Dermatology

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

PASI-score

Toelichting onderzoek

Achtergrond van het onderzoek

N/A

Doel van het onderzoek

N/A

Onderzoeksproduct en/of interventie

Randomization in two groups. One patient group will receive fumarate therapy combined with levocetirizine.
The other patient group will receive fumarate therapy combined with a placebo instead of levocetirizine.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients with known severe psoriasis of the chronic plaque type

2. PASI > 10

3. Age > 18 years

4. Psoriasis therapies cannot be administered starting from 28 days before baseline visit until discontinuation of the study medications at the end of the study.

5. All forms of ultraviolet light therapy are prohibited during the study through week 12, such as PUVA and UVB (including narrow band UVB and excimer laser). Puva is prohibited starting from 28 days before the baseline and UVB is prohibited starting from 14 days before baseline.

6. All forms of topical psoriasis therapies cannot be administered from 14 days before baseline until discontinuation of the study medications through week 12.

7. Investigational or biological drugs are not permitted from 28 days prior to screening visit until discontinuation of the study medication at the end of study.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Pregnancy and breast feeding

2. Patients with Prostate hyperplasia, Glaucoma, Stomach ulcer

3. Patients with liver diseases

4. Patients with kidney diseases

5. Patients with blood test deviations

6. Patients with gastro-intestinal diseases

7. Patients with a history of malignancies

8. Presence of clinically significant renal and hepatic laboratory values (i.e.,male patients with serum creatinine ¡Ý 133 umol/L; female patients with serum creatinine ¡Ý 124 umol/L; ALT, AST, total bilirubin, GGT, or Alkaline Phosphatase > 2.5 times the upper limit of the reference range).

9. Serum lipase impairments (total cholesterol > 6.5 mmol/l, LDL-cholesterol > 2mmol/l, triglyceride > 3 mmol/l).

10. Hemoglobin parameters must satisfy the following criteria:

10.1 hemoglobin < 7.5 mmol/l

10.2 leukocytes > 3.50*10E9/l and < 10*10E9/l

10.3 lymphocytes > 15% and < 50% of the total white cell count.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Open / niet geblindeerd
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-09-2006
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	01-08-2006
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	NL734
NTR-old	NTR744
Ander register	: N/A
ISRCTN	ISRCTN12758639

Resultaten

Samenvatting resultaten
N/A