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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20745

Source
NTR

Brief title
N/A

Health condition

Psoriasis vulgaris

Sponsors and support

Primary sponsor: Erasmus Medical Center Rotterdam, Departement of Dermatology

Intervention

Outcome measures

Primary outcome

PASI-score

Secondary outcome

skin-biopsies

Study description

Background summary

N/A

Study objective

N/A

Intervention

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.

Contacts

Public
Erasmus Medical Center
Dermatology Department
P.O. Box 2040

S. Fallah-Arani
Rotterdam 3000 CA
The Netherlands
+31 (0)10 4639222
Scientific
Erasmus Medical Center
Dermatology Department
P.O. Box 2040

S. Fallah-Arani
Rotterdam 3000 CA
The Netherlands
+31 (0)10 4639222

Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2006
Enrollment:	40
Type:	Anticipated

Ethics review

Positive opinion

Date:	01-08-2006
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	NL734
NTR-old	NTR744
Other	: N/A
ISRCTN	ISRCTN12758639

Study results

Summary results
N/A