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

Submission date	Recruitment status	[ ] Prospectively registered
22/11/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
22/11/2006	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/09/2008	Skin and Connective Tissue Diseases	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NTR744

Study information

Scientific Title

Study objectives
Not provided at time of registration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Randomised placebo-controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Psoriasis

Interventions
Randomisation 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.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Fumarate therapy, levocetirizine

Primary outcome measure
PASI-score

Secondary outcome measures
Skin-biopsies

Overall study start date
01/09/2006

Completion date
01/01/2008

Eligibility

Key inclusion criteria
1. Patients with known severe psoriasis of the chronic plaque type
2. Psoriasis Area and Severity Index (PASI) more than ten
3. Age more than 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 Psoralen Ultraviolet A therapy (PUVA) and Ultraviolet B (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

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
40

Key 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 more than or equal to 133 umol/L; female patients with serum creatinine more than or equal to 124 umol/L; Alanine Aminotransferase [ALT], Aspartate Aminotransferase [AST], total bilirubin, Gamma-Glutamyl Transferase [GGT], or Alkaline Phosphatase more than 2.5 times the upper limit of the reference range)
9. Serum lipase impairments (total cholesterol more than 6.5 mmol/l, Low Density Lipoprotein [LDL]-cholesterol less than 2 mmol/l, triglyceride more than 3 mmol/l).
10. Haemoglobin parameters must satisfy the following criteria:
a. haemoglobin less than 7.5 mmol/l
b. leukocytes more than 3.50 x 10^9/l and less than 10 x 10^9/l
c. lymphocytes more than 15% and less than 50% of the total white cell count

Date of first enrolment
01/09/2006

Date of final enrolment
01/01/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
Erasmus Medical Center
Rotterdam
Netherlands
3000 CA

Sponsor information

Organisation
Erasmus Medical Center (The Netherlands)

Sponsor details
Department of Dermatology and Venereology
P.O. Box 2040
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Not defined

Funder Name
Not provided at time of registration

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration