A comparison of the efficacy of oral fumarate and methotrexate therapy in the treatment of severe psoriasis.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21850

Source
NTR

Brief title
N/A

Health condition

Psoriasis vulgaris

Sponsors and support

Primary sponsor: Erasmus medical centre (Erasmus MC) Rotterdam, Departement of Dermatology and Venereology

Intervention

Outcome measures

Primary outcome

PASI (psoriasis area severity index-)-score.

Secondary outcome

PGA (physician global assessment)
Blood and urine samples will be collected for laboratory tests.

Study description

Background summary

Psoriasis is a T-cell mediated skin disease affecting 2-3 % of the world's population. Methotrexate is known to be effective in the treatment of severe psoriasis. Like other currently used systemical treatments for psoriasis. Methotrexate has a significant potential for toxicity. It can cause bone-marrow toxicity, hepatic fibrosis, stomatitis, gastrointestinal intolerance, fever, alopecia and it is teratogenic. The anti-psoriatic drug, Fumaderm® or Fumarate '120', further referred to as 'fumarate therapy' or 'fumarates' has proven to be effective in psoriasis vulgaris. Systemic therapy with fumarates may be given to patients for prolonged periods because of its lack of serious side effects. Commonly reported side-effects of fumarates are flushing, gastrointestinal complaints, nausea, and tiredness. These side-effects usually occur during the induction of fumarate therapy.
This current study is designed to:

1. determine the efficacy of systemic fumarate and methotrexate therapy.

2. investigate the advantages of fumarate therapy in comparison with methotrexate therapy.

3. determine which of the two therapies induce a PASI reduction of ≥ 75 first.

4. investigate whether the change of PASI-score of patients treated with fumarates or methotrexate is maintained for a long period after cessation of the therapy.

Study objective

N/A

Study design

N/A

Intervention

Patients will be randomized to receive either fumarate or methotrexate therapy.
The total study-duration will be 16 weeks with a follow-up for 4 weeks.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients should be at least 18 years with a maximum age of 65 years.

2. Patients should suffer from chronic plaque-type psoriasis.

3. PASI >8.

Exclusion criteria

1. Patients with other forms of psoriasis like psoriasis guttata or pustulosa.

2. Patients who have received prior treatment with either fumarates or methotrexate.

3. Patients in need of co-medications that may influence psoriasis, the clinical response of either fumarates or methotrexate, or toxitcity of either fumarates or methotrexate.

4. Acute infections requiring antimicrobial therapy or associated with HIV infection.

5. Hepatitis B, C, HIV.

6. Pregnancy, breast-feeding, desire to have children within 3 months after the cessation of therapy, unacceptable or non-compliant contraception.

7. Body-weight under 50 kg.

8. Obesity (Body mass Index 30-40).

9. Relevant cardiovascular, pulmonary, celebral, neurological, hematological, liver or renal impairments.

10. (Insulin-dependent) Diabetes mellitus.

11. Hypertension defined as diastolic pressure higher than 95 mmHg, or a systolic pressure higher than 160 mmHg.

12. High risk of liver function disturbances like genetic abnormalities, relevant abnormality in the liver by ultrasound.

13. Chronic constrictive heart failure.

14. History of arsenic medication, malignancy, carcinogenic therapy, immunosuppressive medication.

15. Anemia, leukopenia, thrombocytopenia, high serum creatinin, any blood transfusions.

16. Drug or alcohol abuse.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2006
Enrollment:	60
Type:	Actual

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	NL733
NTR-old	NTR743
Other	: N/A
ISRCTN	ISRCTN76608307

Study results

Summary results
N/A