

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

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<b>Registration date</b> 22/11/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 23/09/2021	<b>Condition category</b> Skin and Connective Tissue Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr S Fallah-Arani

**Contact details**  
Erasmus Medical Center  
Dermatology Department  
P.O. Box 2040  
Rotterdam  
Netherlands  
3000 CA  
+31 (0)10 4639222  
s.fallaharani@erasmusmc.nl

## Additional identifiers

**Protocol serial number**  
NL733 (NTR743)

## Study information

**Scientific Title**

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

### **Study objectives**

Psoriasis is a T-cell mediated skin disease affecting 2 to 3% of the worlds 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 Psoriasis Area and Severity Index (PASI) reduction of more than or equal to 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.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Ethics approval received from the local medical ethics committee

### **Primary study design**

Interventional

### **Study design**

Randomised controlled trial

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Psoriasis

### **Interventions**

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

### **Intervention Type**

Drug

### **Phase**

Not Specified

**Drug/device/biological/vaccine name(s)**

Fumarate and methotrexate therapy

**Primary outcome(s)**

PASI-score

**Key secondary outcome(s)**

1. PGA (Physician Global Assessment)
2. Blood and urine samples will be collected for laboratory tests

**Completion date**

01/10/2006

**Eligibility****Key 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 more than 8

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Not Specified

**Key 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 toxicity of either fumarates or methotrexate
4. Acute infections requiring antimicrobial therapy or associated with Human Immunodeficiency Virus (HIV) infection
5. Hepatitis B, C, HIV
6. Pregnancy, breast-feeding, desire to have children within three months after the cessation of therapy, unacceptable or non-compliant contraception
7. Body-weight under 50 kg
8. Obesity (Body mass Index 30 to 40)
9. Relevant cardiovascular, pulmonary, cerebral, 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

**Date of first enrolment**

01/09/2006

**Date of final enrolment**

01/10/2006

## Locations

**Countries of recruitment**

Netherlands

**Study participating centre****Erasmus Medical Center**

Rotterdam  
Netherlands  
3000 CA

## Sponsor information

**Organisation**

Erasmus Medical Center (The Netherlands)

**ROR**

<https://ror.org/018906e22>

## Funder(s)

**Funder type**

Not defined

**Funder Name**

Not provided at time of registration

## Results and Publications

### Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

Not provided at time of registration

#### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		22/12/2010	23/09/2021	Yes	No