

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

**Submission date**  
22/11/2006

**Recruitment status**  
No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**  
22/11/2006

**Overall study status**  
Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**  
23/09/2021

**Condition category**  
Skin and Connective Tissue Diseases

☐ Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

## 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

### Study design

Randomised controlled 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**

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 measure**

PASI-score

### **Secondary outcome measures**

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

### **Overall study start date**

01/09/2006

### **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

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Not Specified

## **Target number of participants**

60

## **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

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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

**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