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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

Registration date
22/11/2006

Overall study status
Completed

Last Edited
23/09/2021

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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

Study design
Randomised controlled trial

Primary study design
Interventional

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 toxitcity 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, 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

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?
Results article		22/12/2010	23/09/2021	Yes	No