Safety and efficacy of efalizumab in combination with methotrexate in patients with severe psoriasis: a comparative study.

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The objective of this study is to assess the safety and efficacy of efalizumab combined with methotrexate compared with efalizumab monotherapy in adult patients (aged > 18 years) with moderate to severe psoriasis.

Ethical review	Approved WMO
Status	Pending
Health condition type	Epidermal and dermal conditions
Study type	Interventional

Summary

ID

NL-OMON31349

Source
ToetsingOnline

Brief title
Efalizumab methotrexate

Condition

- Epidermal and dermal conditions

Synonym
Psoriasis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud

Source(s) of monetary or material Support: Er is een verzoek ingediend voor een "unrestricted grant" bij de firma Serono. Medicatie wordt vergoed via de eigen ziektekostenverzekering van de patiënt.,Serono

Intervention

Keyword: Efalizumab, Methotrexate, Psoriasis, Safety

Outcome measures

Primary outcome

The primary endpoint for the study is the number and nature of adverse events

in both treatment arms, representing treatment safety.

Secondary outcome

Secondary endpoints are:

· Mean percent reduction in PASI from baseline at week 12

· PASI50, PASI75 and PASI90 response at all visits

· Changes from baseline PASI at all visits

· Mean Skindex and DLQI changes at week 12 and week 24

Study description

Background summary

Methotrexate was the first effective systemic drug for psoriasis and still is the standard systemic therapy for psoriasis. In contrast, efalizumab is one of the newest systemic treatments for psoriasis. Multiple clinical trials have been conducted in which the efficacy and safety of efalizumab treatment for psoriasis was investigated and established.
The safety and efficacy of efalizumab in combination with methotrexate is not known. Purpose of the study is to treat patients with efalizumab combined with methotrexate and to compare the safety and efficacy of this treatment with efalizumab monotherapy.

Study objective

The objective of this study is to assess the safety and efficacy of efalizumab combined with methotrexate compared with efalizumab monotherapy in adult patients (aged > 18 years) with moderate to severe psoriasis.

Study design

Patients will be randomized to efalizumab combined with MTX or to efalizumab monotherapy.
Each visit, Psoriasis Area and Severity Index (PASI) scores are calculated and adverse events are registered. Furthermore, questionnaires (DLQI, Skindex-29) are administered.
If PASI reduction is less than 50% at week 12, patients randomized to efalizumab monotherapy will get combination treatment of efalizumab and MTX. Patients initially randomized to efalizumab/MTX combination therapy who have reached a less than 50% reduction in PASI at week 12, will be enabled to continue this treatment regimen for a maximum of 24 weeks.

Intervention

Efalizumab will be administered subcutaneous (SC), with an initial dose of 0.7 mg/kg/week, followed by 1.0 mg/kg/week. MTX will be administered orally for preference, as a weekly single dose of 15 mg. In case of intolerance (for example, gastrointestinal complaints) after oral MTX administration, MTX will be prescribed as a subcutaneous or intramuscular variant.
MTX dosage can be raised (with a maximum of 25 mg) or lowered according to the judgment of the physician.
In each visit, blood will be taken by venipuncture for laboratoy analysis.

Study burden and risks

There are no safety data about efalizumab/MTX combination therapy.

Contacts

Public
Universitair Medisch Centrum Sint Radboud

Rene Descartesdreef 1
6525 GL Nijmegen
Nederland
Scientific
Universitair Medisch Centrum Sint Radboud

Rene Descartesdreef 1

6525 GL Nijmegen
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Patients must be older than 18 years of age.
- Patients must have a PASI greater than 10, or a PASI greater than 8 in combination with a Skindex-29 > 35.
- Patients must have failed to respond to phototherapy, methotrexate and/or cyclosporin in the past or have a contraindication for using phototherapy or cyclosporin.

Exclusion criteria

- Patients who have non-plaque forms of psoriasis (eg, erythrodermic, guttate or pustular).
- Patients who have current drug-induced psoriasis.
- Female patients who are pregnant, nursing and both men and women who are planning pregnancy during the study period or during the six months after receiving the last dose of study medication.
- Patients with severe other diseases.

Study design

Design

Study phase: 4

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2007
Enrollment:	30
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Methotrexate
Generic name:	Methotrexate
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Raptiva
Generic name:	Efalizumab
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	30-10-2007
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
EudraCT	EUCTR2007-001630-14-NL
CCMO	NL17292.091.07