The effect of adalimumab on immune markers in lesional psoriatic skin.

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To find out the dynamics of cell biological changes in lesional skin during treatment with adalimumab. Secondary objectives:- To find out whether adalimumab treatment results in (1) a reduction of T cell subsets, (2) normalization of proliferation...

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

Summary

ID

NL-OMON32160

Source
ToetsingOnline

Brief title
Adalimumab cell biology cohort study

Condition

- Epidermal and dermal conditions

Synonym
Plaque psoriasis, Psoriasis vulgaris

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W,Abbott,Abbott B.V.

Intervention

Keyword: Adalimumab, Innate and adaptive immunity, Psoriasis, T cell subsets

Outcome measures

Primary outcome

The PASI score at all visits.

Cell biological parameters in the punch biopsies for T cells, innate immunity

and epidermal proliferation.

Secondary outcome

Not applicable.

Study description

Background summary

During effective antipsoriatic treatment virtually all abnormalities in the psoriatic lesion improve. However, it is feasible that some changes are mandatory for a clinical effect as a *conditio sine qua non* and other changes are just the result of the improvement. The study is an attempt to find out whether some abnormalities normalize before clinical improvement and may have a predictive effect.

Study objective

To find out the dynamics of cell biological changes in lesional skin during treatment with adalimumab.

Secondary objectives:
- To find out whether adalimumab treatment results in
(1) a reduction of T cell subsets,
(2) normalization of proliferation and differentiation characteristics and
(3) a reduction of parameters for innate immunity
- To find out the order in which the above mentioned parameters show an alteration.
- To correlate the alteration of cell biological parameters with clinical improvement.

The hypothesis is that certain cell biological parameters normalize before clinical improvement and that improvement of such a parameter is mandatory and predictive for clinical efficacy.

Study design

An observational open label study with invasive measures.

Study burden and risks

The 10 patients will treated with adalimumab for reason that there are clinical indications for treatment selection before the decision as to participate in the study will be made. The biopsies of the skin (6 in total) heal with only a minimal chance of scar formation. The benefit for the patient is that which can be expected form the standard treatment with adalimumab. A further insight in the mode of action is what the investigators expect from this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Subjects 18 years of age or older who have moderate to severe plaque psoriasis, as defined by PASI score >= 10 or PASI score >= 8 AND Skindex total score > 35 at the baseline (week 0) visit. Patients have failed, are intolerant or have contraindications to methotrexate, PUVA and cyclosporin.

Exclusion criteria

- Known history of allergic reaction or significant hypersensitivity to the constituents of adalimumab.
- Systemic therapy for psoriasis for at least 4 weeks prior to Baseline; except for biologic therapies which must be discontinued at least 12 weeks prior to enrolment.
- Topical psoriasis therapy for at least 2 weeks prior to Baseline, except for non-corticosteroid shampoos, bland emollients and low potency topical corticosteroids on the palms, soles, face, inframammary area, and groin only.
- Use of PUVA for at least 4 weeks prior to Baseline.
- Use of oral or injectable corticosteroids for at least 4 weeks prior to Baseline and during the study.
- Use of medication which may aggravate psoriasis: β blockers, antimalaria drugs, NSAID and lithium carbonate.
- Use of tanning beds, excessive sun exposure, or phototherapy (UVB, UVA), for at least 2 weeks prior to Baseline.
- Other active skin diseases or skin infections (bacterial, viral or fungal) that may interfere with evaluation of psoriasis.
- History of listeriosis, histoplasmosis, untreated TB, persistent chronic infections.
- Recent active infections requiring hospitalization or treatment with intravenous (IV) anti-infectives within 30 days or oral anti-infectives within 14 days prior to the Baseline visit.
- Immune deficiency, history of HIV or is immunocompromised.
- Use of anti-retroviral therapy.
- Positive Hepatitis B or C (previous infection).
- History of neurologic symptoms suggestive of central nervous system demyelinating disease.
- Malignancies other than successfully treated non-metastatic cutaneous squamous cell of basal cell carcinoma, or cervical carcinoma in situ.
- Erythrodermic, generalized pustule, new onset guttate, or medication-related or exacerbated psoriasis vulgaris.
- Subject has a poorly controlled medical condition.
- Female subject who is pregnant or breast-feeding or has positive serum pregnancy test at screening or considering becoming pregnant during the study or within 5 months after the

last dose of adalimumab.
- History of keloid formation following wounding.
- Investigator considers the subject unsuitable for adalimumab for any reason.

Study design

Design

Study phase:	4
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2008
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Humira
Generic name:	Adalimumab
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	07-11-2008
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	EUCTR2008-001952-32-NL
CCMO	NL22745.091.08