Optimising adalimumab treatment in psoriasis with concomitant methotrexate.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24479

Source
NTR

Brief title
OPTIMAP-study

Health condition

Moderate to severe psoriasis

Sponsors and support

Primary sponsor: Academic Medical Center, University of Amsterdam, Amsterdam, the Netherlands
Source(s) of monetary or material Support: self funded

Intervention

Outcome measures

Primary outcome

The drug survival at one year.

Secondary outcome

-Efficacy expressed as the proportion of patients achieving PASI 75 and 90 at week 13, 25, 37 and 49 and reduction of absolute PASI at these timepoints;
-Change in PGA (patient global assessment) and IGA (investigator global assessment);
-Average adalimumab serum trough concentrations and ADA titers;
-Change in impact on Quality of life (Skindex 29 and DLQI);
-Treatment satisfaction (measured by TSQM);
-Occurrence of (serious) adverse events;
-Patient characteristics (age, gender, ethnicity, BMI, PsA, smoking, alcohol use, disease duration, disease severity by PASI, concomitant medication, naïve for biologics versus non-naïve (perhaps specified per biologic), trial medication and potential other co-variates (e.g. genetic polymorphisms).

Study description

Background summary

Adalimumab is een waardevolle behandeling voor patiënten met matige tot ernstige psoriasis indien andere behandelingen, zoals topicale therapie, fototherapie en systemische middelen hebben gefaald of gecontra-indiceerd zijn. Neutraliserende antidrug anti lichamen (ADA) tegen adalimumab kunnen de werkzaamheid van adalimumab beïnvloeden en verkorten de drug survival (de duur dat het medicijn werkzaam is). Sommige studies hebben gemeld dat tot 50% van de psoriasis patiënten behandeld met adalimumab ADA ontwikkelen. Er zijn aanwijzingen dat methotrexaat de vorming van ADA verminderd. In dit onderzoek wordt onderzocht of de combinatie behandeling van adalimumab en methotrexaat een verbeterde drug survival, verhoogde effectiviteit en een goede tolerantie heeft in vergelijking met adalimumab monotherapie.

Study objective

The drugsurvival in the combination group will be better than the survival in the monotherapy group.

Study design

week 13, 25, 37 and 49

Intervention

adalimumab versus adalimumab plus methotrexate

Contacts

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Eligibility criteria

Inclusion criteria

-Have a diagnosis of moderate to severe plaque psoriasis (PASI≥8 at time of screening);

-Is a candidate for the treatment with biologic drugs according to the pertaining guidelines;

-Willing and able to use an adequate contraceptives during the study (all men and pre-menopausal women);

-Adalimumab therapy will be started for the treatment of psoriasis

-Signed informed consent.

Exclusion criteria

-History of significant MTX or adalimumab toxicity, intolerability or contraindication

-Prior treatment with adalimumab

-Age < 18 years;

- Known liver or kidney malfunction

- Alcoholabuse

-Blooddyscrasia like bonemarrowhypoplasia, leukocytopenia, thrombocytopenia or a significant anemia

-Known severe or chronic infections like tuberculosis or HIV

- Ulcers in the oral cavity or known active ulcers in digestive tract

-Pregnant and nursing women.

-Need for live vaccinations

-Other immunosuppressive medication (prednisone, mycofenolaatmofetyl (Cellcept e.g.), ciclosporine (Neoral e.g.), sirolimus (Rapamune), systemic tacrolimus (Prograft e.g.) e.g.)

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-03-2014
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion

Date:	07-04-2014
Application type:	First submission

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
NTR-new	NL4359
NTR-old	NTR4499
Other	METC AMC Amsterdam : Project 2013_346

Study results