Prospective follow-up study of adalimumab treatment in ankylosing spondylitis: efficacy with focus on uveitis

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Objectives1. Determine efficacy of adalimumab as the first biologic agent or after previous use of other anti-TNF blocking agent. Efficacy will be evaluated by means of the ASAS 20% response criteria.2. Determine the efficacy of adalimumab on...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Joint disorders
Study type	Observational non invasive

Summary

ID

NL-OMON30515

Source
ToetsingOnline

Brief title
Adalimumab, uveitis and ankylosing spondylitis

Condition

- Joint disorders

Synonym
Ankylosing spondylitis, Bechterew's disease

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Abbott

Intervention

Keyword: adalimumab, ankylosing spondylitis, uveitis

Outcome measures

Primary outcome

Primary:

- ASAS 20% response

- occurrence of attacks of uveitis.

Secondary outcome

Secondary: adverse events, improvement of mobility, swollen joints,

inflammatory markers, and radiographic progression.

Study description

Background summary

Until recently, there were only few therapeutic options to treat AS. Efficacy is only proven for treatment with NSAIDs and in some cases sulphasalazine. TNF blocking agents, like etanercept and infliximab are very effective in these patients. However, the efficacy on extra spinal manifestations as uveitis appear to differ between these drugs, with a better efficacy, i.e. less (severe) attacks with infliximab in comparison to etanercept.
The efficacy of adalimumab on uveitis has not yet been investigated. These attacks of anterior uveitis occur frequently in AS and up to 30% of the patients suffer from uveitis and ultimately it can result in glaucoma and severe visual impairment if left untreated.
Adalimumab is another TNF-blocking agent which is currently investigated in several clinical trials for ankylosing spondylitis. Ongoing studies indicate that adalimumab is effective in AS. and recently adalimumab is registered for.
This study aims to monitor the efficacy on AS and the extra spinal manifestations like uveitis.

Study objective

Objectives
1. Determine efficacy of adalimumab as the first biologic agent or after

previous use of other anti-TNF blocking agent. Efficacy will be evaluated by means of the ASAS 20% response criteria.
2. Determine the efficacy of adalimumab on uveitis.
3. Determine safety of adalimumab by monitoring of adverse events.

Study design

Methods
The visits occur at screening, baseline, 4, 12 weeks, and every 3 months thereafter. The follow-up period is aimed to reach at least between one and three years.
During the follow-up the following parameters will be measured:
Every visit: registration of adverse events, occurrence of extra-spinal manifestations, physical examination (joint assessments a.o.), questionnaires and laboratory tests.

At baseline and every 6 months a screening by the ophthalmologist will be performed with special attential for uveitis. will be compared with the historical controls (the attacks per year before therapy

Study burden and risks

None, exept a limited extra amount of blood, obtained during regular venapuntures

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

Ankylosing spondylitis according to the modified New York criteria, who will start with adalimumab.

Exclusion criteria

1. Persistent chronic or active infections
2. History of amlignancy
3. Immuno-compromised conditions.
4. History of central nervous system (CNS) demyelinating disease.
5. Female subject who is pregnant or breast-feeding or considering becoming pregnant during the study.
6. Known history of allergic reaction or significant hypersensitivity to the constituents of adalimumab.

Study design

Design

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

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	30-03-2007
Enrollment:	100
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	EUCTR2006-006770-13-NL
CCMO	NL15746.048.06