therapeutic drug monitoring: towards tailored dosing of adalimumab in rheumatoid arthritis

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To examine disease activity in patients with high serum adalimumab concentration who are randomly assigned to continuation of the regular dose or to dose interval prolongation and to examine the cost-effectiveness of this therapeutic drug monitoring...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Autoimmune disorders
Study type	Interventional

Summary

ID

NL-OMON41716

Source
ToetsingOnline

Brief title
therapeutic drug monitoring of adalimumab in rheumatoid arthritis

Condition

- Autoimmune disorders

Synonym
rheumatoide arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Reade, centrum voor Revalidatie en Reumatologie
Source(s) of monetary or material Support: Reumafonds

Intervention

Keyword: adalimumab, rheumatoid arthritis, therapeutic drug monitoring

Outcome measures

Primary outcome

Similar *DAS28 in patients with high serum adalimumab concentrations who are randomly assigned to continuation of the regular dose or to dose interval prolongation. A clinically relevant difference in disease activity is defined as a *DAS28 > 0.6.

Secondary outcome

Cost-effectiveness of therapeutic drug monitoring in rheumatoid arthritis patients responding to adalimumab.

Study description

Background summary

Treatment with biologicals is based on the principle of *one size fits all*. In the dosing scheme, patients characteristics or pharmacokinetic aspects are not taken into account. In addition, when a patient responds well to the drug, the question whether the dose can be de-escalated or the drug can be discontinued, remains unanswered. Based on literature, dose de-escalation seems to be safe with regard to disease activity and might be beneficial in lowering the risk of adverse events. An important additional aspect is the large amount of costs that can be saved when the same response rates are achieved with less medication.

Study objective

To examine disease activity in patients with high serum adalimumab concentration who are randomly assigned to continuation of the regular dose or to dose interval prolongation and to examine the cost-effectiveness of this therapeutic drug monitoring strategy.

Study design

Open randomised controlled study of therapeutic drug monitoring in 112 RA patients treated with adalimumab.

Intervention

Patients with high adalimumab concentrations will be randomly assigned for continuation of adalimumab every other week or prolongation of the dosage interval to once every 3 weeks. Patients assigned to continuation of adalimumab treatment prolong the dosage interval to once every 3 weeks for an additional 6 months after 6 months of continuation of the original dosage. The endpoint of the study for patients assigned to prolongation of the dosage initially, will be 6 months after inclusion.

Study burden and risks

We hypothesize that in patients with high adalimumab concentrations and dose interval prolongation disease activity remains stable, however, an increased disease activity risk can not be excluded.

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

RA according to the ACR 1987 criteria
Adalimumab treatment for at least 28 weeks
Trough adalimumab level > 12 mg/L
Treating rheumatologist is convinced of the benefit of adalimumab continuation
Written informed consent

Exclusion criteria

Scheduled surgery in the next 6 months or other pre planned reasons for treatment discontinuation.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-11-2012
Enrollment:	112
Type:	Actual

Ethics review

Approved WMO Date:	04-10-2012
Application type:	First submission
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)
Approved WMO Date:	31-08-2015
Application type:	Amendment
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)

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
CCMO	NL41362.048.12
Other	NTR: 3509

Study results

Date completed:	31-01-2016
Actual enrolment:	55