Therapeutic drug monitoring: Toward tailored dosing of adalimumab in rheumatoid arthritis.

No registrations found.

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

Summary

ID

NL-OMON29559

Source
Nationaal Trial Register

Health condition

rheumatoid arthritis
adalimumab
therapeutic drug monitoring

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

Similar deltaDAS28 in patients with high serum adalimumab concentrations who are randomly assigned to continuation of the regular dose or to dose interval prolongation.

Secondary outcome

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

Study description

Background summary

Rationale:

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.

Objective:

To examine response of 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 RA patients treated with adalimumab.

Intervention:

Patients with high adalimumab concentrations will be randomly assigned to continuation of adalimumab every other week or prolongation of the dosage interval to once every 3 weeks. Patients will be followed for 6 months.

Main study parameters:

Adalimumab serum concentrations define whether a patient is suitable for inclusion and randomisation. Adalimumab serum concentrations, disease activity and cost related parameters will be measured during follow-up.

Nature and extent of the burden:

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.

Study objective

We hypothesize that in rheumatoid arthritis (RA) patients responding to adalimumab, with high adalimumab serum concentrations at least 28 weeks after treatment initiation:

1. Lowering the serum concentrations through dose interval prolongation will not influence disease activity and hence;

2. Through lower costs, dose interval prolongation will be more cost–effective than the traditional treatment scheme.

Study design

-2 weeks, 0, 2 and 6 months.

Intervention

Patients with high adalimumab concentrations will be randomly assigned to continuation of adalimumab every other week or prolongation of the dosage interval to once every 3 weeks. Patients will be followed for 6 months.

Contacts

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Eligibility criteria

Inclusion criteria

1. RA according to the ACR 1987 criteria;

2. Adalimumab treatment for at least 28 weeks;

3. Treating rheumatologist is convinced of the benefit of adalimumab continuation;

4. Written informed consent.

5. Trough adalimumab level > 8.0 mg/L

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2012
Enrollment:	102
Type:	Anticipated

Ethics review

Positive opinion

Date:	05-07-2012
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	NL3361
NTR-old	NTR3509
Other	METC Slotervaartziekenhuis : P1245
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A