Randomised controlled trial evaluating strategies to optimize disease activity control in RA patients treated with infliximab in clinical practice.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON29750

Source
ToetsingOnline

Brief title
RE3, REtain REmicade REsponse

Condition

- Joint disorders

Synonym
Arthritis, Rheumatoid Arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Schering-Plough

Source(s) of monetary or material Support: Schering Plough

Intervention

Keyword: Early disease flare, Remicade, Rheumatoid Arthritis, treatment strategies

Outcome measures

Primary outcome

The primary study eindpoint is the difference between the mean of the DAS28 in each dose intensification arm as compared to the mean in the control arm. The aim is to show that this differende between the means is at least 0.6.

Secondary outcome

Secondary study endpoints:

- Bone turnover as measured by urine CTX-II
- Percentage of patients who regain initial (w6) response
- Percentage of patients who drop out for (continued or new) flare
- EULAR response, ACR response week 14/22- week 38/46
- Other DAS28 cut-off scores for flare and response
- Quality of Life measuremment: RA-QOL
- Pharmaco-economic evaluation
- % of patients who need rescue medication

Study description

Background summary

Over 60% of rheumatoid arthritis (RA) patiens respon to induction of infliximab treatment (infusion of 3 mg/kg at week 0, 2, 6) Within this group of responders

the majority of patients show a sustained response. In an estimated 15- 20% of patients initiated, however, the response shown at week 6 is followed by a disease flare when the patient is switched to one infusion every 8 weeks.

Study objective

At present there are no validated parameters that predict how a patient will respond to infliximab treatment.
In this study they like to investigate why a certain persentige of patients do have a disease flaire. This suggests that infliximab levels in these patients fall below a certain efficacy threshold.
Based on this, two approaches have been suggested so as to optimize treatment for these patients.

Study design

The patients will be devided in three groups (by randomisation with the IVRS system).

Randomisation groups:
1. Control: same stable dose 3mg/kg every 8 weeks;
2. Increased frequency: stable dose 3mg/kg every 6 weeks
3. Increased dose: one extra vial to previous dose; every 8 weeks.

The patients of the control group and the increased dose group (every 8 weeks) are double-blind.
The patients who receive medication every 6 weeks are "open"

Intervention

Randomisation groups:
1. Control: same stable dose 3mg/kg every 8 weeks;
2. Increased frequency: stable dose 3mg/kg every 6 weeks
3. Increased dose: one extra vial to previous dose; every 8 weeks

Study burden and risks

The patient has 8 visits in a period of 24 weeks.
During the study al adverse events that the patient reports during the study will be followed up and judged. The patient fills in at every visit a Health Assessment Questionaire (HAQ) During visit 2,5 and the final visit a SF-36v2 will be filled in.
At every visit a DAS 28 score will be done. (VAS, laboratory assesments and jointsscore).
Severe adverse events must be reported in 24 hours toward the sponsor and the

appropriate Institutional FEview Board or Independent Ethics Committee.

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

Subject has RA according to ACR criteria
Subject aged 18 years or more
Subject received the standard Remicad dosing schedule as per the EU label: 3mg/kg weeks 0, 2 and 6 followed by 1 or 2 intervals of 8 weeks.
DAS 28 worsening of at least 0.6 between the time of initial response and the next 8 weekly infusion and the resulting DAS28 value

Exclusion criteria

pregnancy
Remicade allergy
patient didn't show an initial response on Remicade (infliximab) during the induction period.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2006
Enrollment:	36
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Remicade
Generic name:	Infliximab
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	17-05-2006
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	10-10-2006
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	16-11-2006
Application type:	Amendment
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	EUCTR2005-001889-13-NL
CCMO	NL11336.091.06