Prospective study on the effects of withdrawal of anti-TNF therapy in patients with rheumatoid arthritis who are in remission- stop-study

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To evaluate the clinical course in RA after cessation of TNF blockade and to determine biomarkers of successful cessation of TNF blockade.

Ethical review	-
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Observational invasive

Summary

ID

NL-OMON34531

Source
ToetsingOnline

Brief title
AMC STOP

Condition

- Joint disorders

Synonym
Rheumatoid arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: remission, Rheumatoid Arthritis, TNF blockade

Outcome measures

Primary outcome

The primary endpoint of the study is:

1. The percentage of patients that sustain drug-free remission 24 months after the cessation of TNF-antagonists

2. Predictors (e.g. clinical parameters, serological and immunological markers) of sustained drug-free remission

Secondary outcome

1. The difference in genetic markers/ epigenetic markers (e.g. genetic polymorphisms/ methylation status) in TNF-* genes that predict sustained drug-free remission in the individual patient

2. Explore new markers, e.g. by micro-array analysis, distinguishing patients with sustained drug-free remission from patients who relapse.

3. Determine the percentage of patients with subclinical synovitis as determined by ultrasound in this group of patients in clinical remission

Study description

Background summary

The ability to predict successful cessation of TNF blockade would have significant implications not only because anti-TNF treatment elevates the risk for adverse events such as infections, but also for financial reasons.

Study objective

To evaluate the clinical course in RA after cessation of TNF blockade and to determine biomarkers of successful cessation of TNF blockade.

Study design

Following a screening period of 2 weeks, patients will be enrolled into a prospective study for a period of 24 months. At baseline they will stop using their current TNF-blocker.

Patients will continue the use of concomitant non-steroidal anti-inflammatory drugs (NSAIDs) and DMARDs in the dosage they used before the start of the trial.

Clinical evaluation of joint pain and swelling will be done at baseline and repeated after 3, 6, 9, 12, 15, 18, 21 and 24 months. Patients will be seen for efficacy and safety assessments in accordance with standard guidelines for clinical practice. In addition an ultrasound of both wrists, all metocarpophalageal joints and proximal interphalageal joints will be done to evaluate possible subclinical synovial hypertrophy.
In total there will be 10 study visits: screening, baseline, 3 months, 6 months, 9 months, 12 months, 15 months, 18 months, 21 months and 24 months. There will be a ± 7 day deviation for all return visits. All visits will be fixed with reference to the baseline visit. Furthermore an withdrawal will take place if a flare occurs and this is not within 7 days of a scheduled assessment and a safety-follow up visit will be done 3 months after withdrawal from the study.

Study burden and risks

n.a.

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

Men/women suffering from rheumatoid arthritis, based on the 2010 American College of Rheumatology/ European league Against Rheumatism (ACR/EULAR) classification criteria for RA will be included in this study.;Patients in ARA functional classes I, II, and III may be included.;In addition, patients must fulfill the following criteria at baseline:
1) DAS 28 * 2.6 for the duration of a minimum of 24 weeks
2) Be > 18 years of age and * 85 years.
3) Stable use of concomitant DMARDs and TNF antagonists for the duration of 24 weeks before baseline

Exclusion criteria

1) The use of oral/ intra-articular corticosteroids within 6 months prior to baseline
2) Pregnancy
3) Breastfeeding
4) Subjects who are impaired, incapacitated, or incapable of completing study related assessments.
5) Subjects who meet diagnostic criteria for any other rheumatic disease (e.g., lupus erythematous).
6) Subjects with active vasculitis of a major organ system with the exception of rheumatoid nodules.
7) Subjects with current symptoms of severe, progressive, or uncontrolled renal, hepatic, hematological, gastrointestinal, pulmonary, cardiac, neurological, or cerebral disease, or other medical conditions that, in the opinion of the investigator, might place the subject at unacceptable risk for participation in this study.

8) Subjects who have clinically significant drug or alcohol abuse.
9) Inability to give informed consent
10) Mental condition rendering the patient unable to understand the na¬ture, scope and possible consequences of the study and/or evidence of an uncooperative attitude.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-04-2011
Enrollment:	40
Type:	Actual

Ethics review

Not available

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	NL33643.018.10