Influence of B cell depletion therapy (rituximab) on (risk factors of) comorbidity in rheumatoid arthritis

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The objective of this study is to investigate whether there is a change in lipids and bonemarkers and what the frequency of occurence of (riskfactors for) cardiovascular disease, osteoporosis and antibodies during treatment with rituximab.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Observational invasive

Summary

ID

NL-OMON31299

Source
ToetsingOnline

Brief title
B cell depletion therapy in rheumatoid arthritis and comorbidity

Condition

- Cardiac disorders, signs and symptoms NEC
- Autoimmune disorders
- Joint disorders

Synonym
rheumatoid arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: comorbidity, rheumatoid arthritis, rituximab

Outcome measures

Primary outcome

Primary study variables will be a change in lipids (total cholesterol, HDL, LDL and TG) and lipoproteins (Lp-a, Apo-A1, Apo-B), bonemineral densitiy (DEXA) and bonemarkers (osteocalcine, OPG, *-CTx and RANKL) and antibodyformation.

Secondary outcome

Secundary study variables will be a change in disease activity (DAS 28), functional capacity (HAQ-score), radiologic progression (Sharp van der Heyde score) and B cell count.

Study description

Background summary

Since the year 2000 rheumatoid arthritis (RA) can be treated with immunomodulating drugs (biologicals). One of these agents is rituximab, which results in B cell depletion by binding selectively on the celmembraneprotein CD 20. Recently it was found that B cells play a major role in the pathogenesis of rheumatoid arthritis. In rheumatoid arthritis there is a high prevalence and incidence of comorbidity, i.e. osteoporosis and cardiovascular diseases. It is unclear what the influence of rituximab is on (these riskfactors for) this comorbidity in rheumatoid arthritis. Moreover, it's unknown whether antibodies against rituximab will appear during the treatment with rituximab.

Study objective

The objective of this study is to investigate whether there is a change in lipids and bonemarkers and what the frequency of occurence of (riskfactors for) cardiovascular disease, osteoporosis and antibodies during treatment with

rituximab.

Study design

prospective observational multicentre study

Study burden and risks

Patients will be seen eight times for collecting data (including questionnaires, laboratory and radiologic tests) during the 2 years follow up.

Contacts

Public
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
1081 HV Amsterdam
Nederland
Scientific
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
1081 HV Amsterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

According to the thesis of the Dutch association of rheumatology (NVR): treatment with rituximab of rheumatoid arthritis patients:
- rheumatoid arthritis diagnosed according to the ACR criteria 1987
- active rheumatoid arthritis
- previous failure of TNF alpha blocking

Exclusion criteria

- malignity
- active tuberculosis or other active infection
- pregnancy and lactation
- severe heart failure (NYHA IV) or other cardiac disease
- hypersensitivity to one of the active substances of rituximab or murine proteins

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-03-2008
Enrollment:	50
Type:	Actual

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
CCMO	NL18857.029.07