Implementation of Cardiovascular Risk management for patients with Rheumatoïd Arthritis (I-CaRe)

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Coronary artery disorders
Study type	Observational non invasive

Summary

ID

NL-OMON41344

Source
ToetsingOnline

Brief title
I-CaRe

Condition

- Coronary artery disorders
- Autoimmune disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
cardiovascular disease and atherosclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Jan van Breemen Instituut

Source(s) of monetary or material Support: Reade revalidatie en reumatologie

Intervention

Keyword: cardiovascular disease, cardiovascular risk management, implementation project, rheumatoid arthritis

Outcome measures

Primary outcome

The percentage of RA patients at baseline, 1, 2, 3, 4 and 5 years,

participating in this implementation study and their assessed risk profile

The calulated difference between 10-years cardiovascular mortality risk at

baseline, 1, 2, 3, 4 and 5 years.

Secondary outcome

First we will assess the cardiovascular risk profile of all participating RA

patients. Then we will calculate the percentages of patients with untreated

hypertension, hypercholesterolemia and/or diabetes mellitus type 2 separately.

The incidence of cardiovascular events, like angina pectoris, myocardial

infarction, ischemic heart disease, heart failure, PCI, CABG, CVA, TIA,

carotid-endarteriectomy, signs of periferal atherosclerosis. We will compare

these incidence rates with the incidence rates of the CARRE study.

The effect of antihypertenive medication and statins in RA patients after 1,

2, 3, 4 and 5 years of CV-RM.

Compliance of lifestyle advices and prescribed medication

Patients satisfaction with offered care, assessed with a questionnaire

Study description

Background summary

The risk for fatal and non-fatal cardiovascular disease (CVD) in patients with rheumatoid arthritis (RA) is doubled in comparison with the general population and there is accumulating evidence (CARRÉ study) that this enhanced cardiovascular risk is similar to that of diabetes mellitus (DM), a well known and established cardiovascular risk factor.
Research has proven that risk factors for CVD, like high cholesterol, hypertension, smoking, obesity and diabetes are not the only factors responsible for the higher cardiovascular risk in RA patients. Accumulating evidence indicates that inflammation plays an important role as atherosclerosis is in fact an inflammatory disease. Another factor that can play a role is under treatment of cardiovascular co morbidity in RA, for example there is accumulating evidence that hypertension is frequently undertreated in RA.
The fact that the cardiovascular risk is higher in patients with RA makes it necessary to investigate if risk reduction treatment, which has been effective in other risk groups, is also effective in reducing the cardiovascular risk in RA patients

Study objective

The main aim of this implementation research is to systematically screen all RA patients of Reade rheumatology and revalidation centre in Amsterdam for their cardiovascular risk profile and if necessary to treat them for cardiovascular risk factors according to the guidelines of Amsterdam: *Cardiovascular Risk management in Rheumatoid Arthritis (CV-RM)**. We will calculate the 10-years cardiovascular mortality risk at baseline, 1, 2, 3, 4 and 5 years to see if this risk reduces through CV-RM implementation.

secondary objectives are: determining undertreatment of cardiovascular risk factors in RA patients, assessing incidence of cardiovascular disease after CV-RM implementation and patients compliance and satisfaction with offered care.

*http://www.nvr.nl/uploads/237/144/Amsterdamse_CV-RA_richtlijn_30_mei_2007.pdf

Study design

The primary objective of this project is the implementation of cardiovascular risk management in rheumatoid arthritis patients. First of all the cardiovascular risk profile of all rheumatoid arthritis patients of Reade

rheumatology and revalidation centre will be assessed by a nurse practitioner. Subsequently, we will determine the 10-years cardiovascular mortality risk in a percentage for all patients using the Systematic Coronary Risk Evaluation (SCORE)-risk function. Additionally, this risk percentage will be multiplied with a factor 1.5 to adjust for the higher cardiovascular risk in RA. All patients will receive lifestyle advice from a nurse practitioner. This means that the nurse together with the patient will look at the possibilities for life style changes.

When the calculated 10-years mortality risk is 10% or more treatment with lipid lowering agents and/or antihypertensives is recommended. These patients will be referred to the general practitioner for further follow-up and treatment via a letter or telephone contact.

We will recommend that treatment will be implemented according to the Dutch Guideline Cardiovascular Risk Management 2006 and this can vary from only lifestyle recommendations to treatment with lipid lowering drugs and/or antihypertensives. In all RA patients the cardiovascular risk profile and 10-years cardiovascular risk will again be assessed 1, 2, 3, 4 and 5 years after the start to see if this has improved. At these moments the patients will also receive a questionnaire to assess their lifestyle changes, incidence of cardiovascular disease and the compliance of treatment.

Study burden and risks

The nurse will initiate the screening procedure (assessment of BMI, waist/hip ratio, blood pressure, DAS28 score, medical history, particularly about cardiovascular risk factors, an ECG and the necessary laboratory tests including the lipid profile). With the results the 10-years cardiovascular risk will be assessed. This will take time and effort of the patients, but this is for their own health benefit.
The only extra burden is an extra bloodsample taken for research (approximately 50 cc).

Patients with a 10-years CV-risk of more than 10% will be referred to their general practitioner with the results from the screening and a request for further cardiovascular risk management. When medication for hypertension or hypercholesterolemia are prescribed to a patient, this patient has the risk of side-effects. This can also mean that the patient needs to be checked periodically, which takes time and effort. But the idea is that this will ultimately benefit the patients health.

After one and two years all the RA patients will again be invited for cardiovascular screening by the nurses at Reade revalidation and rheumatology centre. This time they will also receive a questionnaire about compliance and quality of life. We will also assess new cardiovascular events. This will be

done to evaluate the effect of this implementation project.

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

patients who have the diagnosis rheumatoid arthritis according to the ACR classification criteria

Exclusion criteria

no signed informed consent

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-06-2011
Enrollment:	3200
Type:	Actual

Ethics review

Approved WMO

Date:	13-12-2010
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	24-04-2015
Application type:	Amendment
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	NL34407.048.10