Franciscus Reumatoide Artritis en Cardiovasculaire interventie studie

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23703

Source
NTR

Brief title
FRANCIS

Health condition

Cardiovascular disease
Rheumatoid Arthritis
Reumatoide artritis
Hart- en vaatziekten

Sponsors and support

Primary sponsor: Sint Franciscus Gasthuis Rotterdam
Source(s) of monetary or material Support: Sint Franciscus Gasthuis Rotterdam

Intervention

Outcome measures

Primary outcome

Primary outcome measure is the progression (change) of atherosclerosis measured by the carotid

artery intima media thickness (IMT) at 5 years follow-up, adjusted for baseline IMT.

Secondary outcome

1. To investigate if a tight multiple cardiovascular risk reduction program is effective in reducing the number of cardiovascular events (clinical atherosclerosis) in patients with RA compared to usual care;

2. To investigate if there is any difference in reducing the progression of clinical and subclinical atherosclerosis between the low risk tight control group and the parallel cohort of high risk tight control (i.e. RA patients with a cardiovascular risk >10% at baseline). Cardiovascular risk is based on the SCORE model (patient with age 65-70 will be scored as 65 years old);

3. To investigate if novel biomarkers are associated with (or prognostic of) atherosclerosis and IMT in RA patients;

4. To evaluate if serum apoB is a modifiable risk marker in RA;

5. To investigate the relationship between leukocyte activation, skin AGEs and atherosclerosis/progression of IMT;

6. Differences in IMT progression per year between tight control and usual care;

7. SelPatient's adherence to therapy and lifestyle advises is evaluated by a patient questionnaire once a
year. This is a Dutch questionnaire composed from the medical outcome study (a general adherence
questionnaire) and the summary of diabetes self care activities, this latter questionnaire is a questionnaire developed especially for patients with diabetes. But since our interventions in this study
will be similar to those in diabetes the questionnaire applies to our study population. The questions
regarding foot care were excluded.

Study description

Background summary

The study is designed as a randomized, open, parallel clinical trial with a prospective cohort, comparing the tight multiple cardiovascular risk reduction program with usual care. RA patients with a cardiovascular mortality risk >10% at study entry are, after proper assessment of inclusion and exclusion criteria, included in the prospective cohort and monitored and treated according to the tight multiple cardiovascular risk reduction program.

RA patients with a cardiovascular mortality risk <10% at study entry, eligible for study participation, are randomly (1:1) assigned to either of two strategies: (1) conventional therapy for multiple risk factors (‘usual care’) or (2) the tight multiple cardiovascular risk reduction program, i.e. intensive multifactorial intervention involving strict treatment goals. Patients receiving usual care will be treated by their general practitioner for cardiovascular risk factors while patients receiving tight control will be treated according to a well defined program. Each patient’s own rheumatologist will treat the rheumatoid arthritis, following state of the art treatment as described in current RA guidelines, using the DAS28 as score for disease activity. Written informed consent will be obtained from each subject. RA patients with SCORE > 10% will receive tight treatment (prospective cohort alongside the RCT). Patients will visit the outpatient clinic every 6 month during 5 years irrespective of cardiovascular risk and/or randomisation.

Study objective

Strict cardiovascular intervention in RA patients leads to less progression of subclinical and clinical athersosclerosis.

Study design

AGEs will be determined once a year
IMT baseline, 6 months, 1 year, after that once a year.
adherence questionaire after 6-24 months of follow up.

Intervention

In all patients, the RA, will be treated by their rheumatologist, regardless randomization State of the art
treatment as described in current RA guidelines will be followed. Treatment goals is a disease activity
score <2,6 measured by the DAS 28.

Patients in the tight control will receive life-style recommendations and strict medical treatment for cardiovascular risk factors (regardless cardiovascular risk score). Treatment targets are LDL-cholesterol <3,0mmol/L, Blood pressure <140/85mmHg, apolipoproteinB <0,9g/L, HbA1c <6,5%, Tryglicerides (non-fasting) <2,2mmol/L, HDL >1,0mmol/L in Male patients and >1,2mmol/L in female patients, BMI <25kg/m2, smoking cessation.

Treatment takes place according to a predefined protocol. The advice is to start with simvastatine 40mg if LDL-cholesterol or apoB is above target and start with perindopril 4mg when BP is above target. Metformine is the prefered treatment when HbA1C is above target.

Patients in the usual care group will be treated by their general practitioner. No recommendations are made.

Contacts

Public
Kleiweg 500
D.F. Breukelen, van
Rotterdam 3045 PM
The Netherlands
Scientific
Kleiweg 500
D.F. Breukelen, van
Rotterdam 3045 PM
The Netherlands

Eligibility criteria

Inclusion criteria

1. Established RA according to the American College of Rheumatology 1987 Criteria (73);

2. < 70 years old;

3. [for RCT participation only]: Cardiovascular mortality risk according to SCORE (Patient with age 65-70 will be scored as 65 years old) (71) <10%;

4. Written informed consent.

Exclusion criteria

1. Patients with type 1 or type 2 diabetes;

2. Cardiovascular event in history: cerebrovascular attack, acute myocardial infarction, CABG, PTCA
and amputation or PTA due to peripheral artery disease. Patients with claudicatio will only be excluded
when follow up in the outpatient clinic for vascular surgery and/or surgical intervention is necessary.
Patients with aneurysms will not be excluded;

3. Patients with severely decreased kidney function (MDRD ≤30) will be excluded;

4. Patients with contra indications for certain medication due to for example co morbidities.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2011
Enrollment:	316
Type:	Actual

Ethics review

Positive opinion

Date:	20-02-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 34401
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3703
NTR-old	NTR3873
CCMO	NL32669.101.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON34401

Study results

Summary results
N/A