Assessment of endothelial dysfunction and premature atherosclerosis in patients with recent onset Rheumatoid Arthritis, a longitudinal study

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON33873

Source
ToetsingOnline

Brief title
Endothelial dysfunction measured by PWA in early RA, a longitudinal study

Condition

- Other condition
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
rheumatoid arthritis

Health condition

gewrichtsaandoeningen

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W,research projectgelden afdeling reumatologie/immunologie

Intervention

Keyword: Advanced glycation end products, Intima media thickness, Pulse wave analysis

Outcome measures

Primary outcome

-Small artery elasticity

-Intima media thickness

-Advanced glycation end products in de huid

Secondary outcome

- soluble AGE receptor(s-RAGE)

- endothelial activation markers such as VCAM, vWF, trombomoduline

Study description

Background summary

In patients with reumatoid arthritis an increased cardivascular morbidity and mortality is present.
We hypothesize that in achieving disease remission also the cardiovascular risk will decrease. We will inverstigate this using the following parameters:
-Intima media thickness
-Small artery elasticity
-Advanced glycation end products in the skin.

Study objective

In this investigation we want to regain more insight in the cardiovascular risk

profile of RA patients. Also we want to find out which patients should have more attention concerning their cardiovascular risk profile and probably therapy for traditional risk-factors such as hypercholesteolemia and hypertension.

Study design

We willen 60 patienten includeren met recent gediagnosticeerde RA, die nog niet behandeld zijn en bij hen de uitgangswaarden bepalen wat betreft de surrogaatmarkers voor cardiovasculaire ziekte. Na een jaar en na twee jaar herhalen we de metingen.

60 patiewnts will have to be included with recent onset reumatoid arthritis. In these patients the surrogate markers for atherosclerosis (intima media thickness, small artery elasticity and AGE accumulation in the skin) will be assessed before start of the treatment and after one and two years.

Study burden and risks

Measurement of IMT/PWA and AGE's every year during 1,5hrs. A total amount of three measurements in two years gives a total of 4,5hrs

Contacts

Public
Universitair Medisch Centrum Groningen

hanzeplein 1, postbus 30001
9700 RB Groningen
Nederland
Scientific
Universitair Medisch Centrum Groningen

hanzeplein 1, postbus 30001
9700 RB Groningen
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

fulfill the ACR criteria for RA
symptoms< 1 year
age >18 years
not previously received disease modifying antirheumatic drugs.

Exclusion criteria

pregnancy
diabetes
renal impairment(eGFR>60ml/min)
recent surgery
myocardial infarction or sepsis in the last three months

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2009

Enrollment:	60
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO	
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL26277.042.08