Treating the compromised hearts of patients with Rheumatoid Arthritis Â¨C Can we repair the damage?

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We hypothesize that diastolic LV function improves in RA patients responding to anti-inflammatory treatment. Adequate and effective anti-inflammatory treatment can reduce the risk of HFpEF, especially in patients with a high cardiovascular risk...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23785

Bron
NTR

Verkorte titel
REVERSE

Aandoening

rheumatoid arthritis

Ondersteuning

Primaire sponsor: Reade
Overige ondersteuning: Reade/Pfizer

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The difference (%) in diastolic echocardiographic parameters in relation with the difference in disease activity will be described. Determinants of diastolic LV function and disease activity will be studied using linear regression analyses for continuous outcome variables (LV mass, ejection fraction, peak A velocity, Apv - Amv duration, left atrial volume), and logistic regression analyses for binary endpoints (systolic and diastolic dysfunction). Disease activity parameters consist of DAS28 score, CRP, BSE, HAQ and SF-36.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: RA patients have an increased risk for developing heart failure with preserved ejection fraction (HFpEF) compared to the normal population. Accumulating evidence shows that systemic inflammatory disease activity in general plays a pivotal role in development of cardiac dysfunction. We therefore expect the diastolic function to improve in RA patients after aggressive anti-inflammatory treatment with anti-TNF.
Objective: Primary Objective: To investigate diastolic LV dysfunction before and after 6 months anti-inflammatory treatment with TNF blockers in patients with RA, assessed by exercise-stress echocardiography. Secondary objectives: To investigate whether systolic LV function improves in patients with RA during treatment with anti-inflammatory therapy with TNF blockers resulting in lower disease activity.
Study design: A prospective cohort study in RA patients indicated for anti-TNF therapy who undergo exercise-stress echocardiography before start of therapy. Patients with diastolic dysfunction at baseline will undergo a second exercise-stress echocardiography after 6 months anti-TNF treatment.
Study population: Fifty RA patients between 40-70 years with active disease characterized as DAS28≥3.2 AND C-reactive protein >10 mg/l OR erythrocyte sedimentation rate (ESR) >15mm/h).
Intervention (if applicable): N/A
Main study parameters/endpoints: The main study parameter is change in echocardiographic parameters before and after 6 months anti-inflammatory treatment with anti-TNF.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: There are some aspects to this protocol that may cause (some) a limited discomfort, however, we do not expect any severe risks as consequence of the study procedure. This study may improve our understanding of the role of inflammation on cardiac dysfunction and the possible reversibility of cardiac dysfunction. Therefore this is has potential to decrease the risk of development of heart failure with preserved ejection fraction in RA patients.

Doel van het onderzoek

We hypothesize that diastolic LV function improves in RA patients responding to anti-inflammatory treatment. Adequate and effective anti-inflammatory treatment can reduce the risk of HFpEF, especially in patients with a high cardiovascular risk profile.

Onderzoeksopzet

baseline and (if applicable) 6 months follow up

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Diagnosis of:
o RA, according to the ARC/EULAR 2010 criteria (11)
- Active disease (DAS28≥3.2) AND C-reactive protein >10 mg/l OR erythrocyte sedimentation rate (ESR) >15mm/h)
- Minimal knee bending/flexion angle of 90 degrees of both knees.
- Age 40-70 years

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Medical history of myocardial infarction or congestive heart failure NYHA class III/IV.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	03-08-2018
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	19-04-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 46382
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7685
CCMO	NL64203.048.17
OMON	NL-OMON46382

Resultaten