Statins to Prevent Rheumatoid Arthritis (STAPRA)

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The use of atorvastatin in persons at high risk of RA is associated with a reduction in de development of arthritis

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON19910

Bron
Nationaal Trial Register

Verkorte titel
STAPRA

Aandoening

Rheumatoid arthritis, RA, Arthralgia, Atorvastatin, seropositive, ACPA, RF, prevention reumatoide arthritis, artralgie, atorvastatine, seropositief, preventie

Ondersteuning

Primaire sponsor: Amsterdam Rheumatology & immunology Center | Reade
Overige ondersteuning: Reumafonds
Amsterdam Rheumatology & immunology Center | Reade

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The occurrence of clinical arthritis confirmed by a rheumatologist participating in the study.

Toelichting onderzoek

Achtergrond van het onderzoek

Background and hypothesis

Rheumatoid arthritis (RA) affects the joints and can lead to serious disability. In RA, a preclinical phase is often present, in which patients do not have arthritis, but do exhibit specific antibodies, often accompanied by vague joint symptoms and general symptoms. The existence of an at-risk phase enables us to investigate interventions with the goal of preventing the development of RA.
One of the major complications of RA is cardiovascular (CV) disease, which is doubled in comparison to the general population. Inflammation is thought to play an important role in this increased risk. Dyslipidaemia is also present, many years before RA becomes clinically apparent.
Therefore, we hypothesize that statin therapy, due to its combined lipid-lowering and anti-inflammatory effects, may be able to prevent the development of clinical arthritis in persons at increased risk for RA.

Study objective

To investigate whether statin treatment can prevent or delay the development of clinical arthritis in persons at increased risk of RA.

Study population

Persons aged 18 years and older, who are either IgM-RF and ACPA positive or have a high ACPA titer (>3x ULN).

Study design

Multicenter double-blind randomized placebo-controlled trial.

Intervention

Atorvastatin 40 mg or placebo OD will be given to 110 seropositive arthralgia patients in each arm during three years.

Main study parameters

The development of arthritis (¡Ý1 swollen joint) is the primary outcome measure. Serum lipids, calculated 10-year risk of cardiovascular events (in participants aged 40 years and over), changes in cIMT and arterial stiffness are secondary outcome measures.

Doel van het onderzoek

The use of atorvastatin in persons at high risk of RA is associated with a reduction in de development of arthritis

Onderzoeksopzet

After inclusion at baseline patients will be monitored every 3 months for 3 years (in the outpatient clinic or by telephone). Then they will stop taking the medication and will receive one more visit after 1 year.

Onderzoeksproduct en/of interventie

Patients will be randomized for atorvastatin 40 mg or placebo tablets. Patients will be taken their medication for 3 years or until they develop arthritis

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1) Age >= 18 years

2) Seropositive

-IgM-RF and ACPA positive OR

-High ACPA titer (>3x cut-off)

3) With or without current joint pain, but without current clinical synovitis (ultrasound exam should not be performed in case of doubt, since US was shown to be often false-positive in this patient group)

4) Written informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1) Patients with synovitis during clinical examination (any of 44 joints of DAS) at inclusion or synovitis in the past during clinical examination by a rheumatologist.

2) Patients with typical RA erosions on X-rays of hand and feet.

3) In case of inclusion depending on the presence of RF, the presence of situations with possible false-positive RF: known active infection with hepatitis C or Ebstein-Barr virus or recent radiotherapy.

4) Use of statins or other lipid-lowering agents within the last three months.

5) A history of previous use of statins discontinued due to side effects.

6) Patients with an indication for statin therapy according to local guidelines. All patients will be screened pior to randomisation, patients who fall into this category (SBD>180 mmHg, TC/HDL> 8.0 or have a cardiovasculair risk ¡Ã20% (only for patients between 40-70 years old) with SBD>140 mmHg and/ or LDL>2,5 mmol/L (see appendix H)) will be referred to the general practitioner with treatment advice).

7) Previous use of DMARDs other than hydroxychloroquine, or use of hydroxychloroquine

within the last three months.

8) A history of oral or parenteral use of corticosteroids within the last 12 weeks used to treat the current episode of musculoskeletal symptoms.

9) Subjects with current severe, progressive, or uncontrolled hepatic disease (ALT>3x ULN), CK >3x ULN, hematologic disease, gastrointestinal disease, (diabetes with a serum glucose >7.0 mmol/L), pulmonary, cardiac, neurologic, or cerebral disease which, in the opinion of the investigator, might place a subject at unacceptable risk when participating in the study.

10) Subjects who are pregnant or who are breastfeeding or wish to become pregnant.

11) Subjects who currently abuse recreational drugs, or drink alcohol in excess (defined for the purposes of this trial as ¡Ã 21 units of alcohol per week; one unit = 1 glass of wine (125 mL) = 1 measure of spirits = ¡§ö pint of beer).

12) Subjects who have a limited life expectancy.

13) Subjects who are unable to fill out the questionnaires.

14) Subjects who are using ciclosporin (which interacts with statins).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-08-2015
Aantal proefpersonen:	220
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	26-06-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 44914
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5036
NTR-old	NTR5265
CCMO	NL47550.048.13
OMON	NL-OMON44914

Resultaten

Samenvatting resultaten
N/A