Apremilast and cardiometabolic effects

Gepubliceerd: 16-05-2018 Laatst bijgewerkt: 13-12-2022

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

Samenvatting

ID

NL-OMON19880

Bron
NTR

Aandoening

Psoriatic arthritis (PsA)

Ondersteuning

Primaire sponsor: Reade, outpatient rheumatology clinic
Overige ondersteuning: Celgene

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- Body composition =: this will be assessed using whole body DEXA, and body composition will be analyzed for whole-body and segmental lean soft tissue, fat mass and body fat percentage using DXA.

Toelichting onderzoek

Achtergrond van het onderzoek

Introduction: Psoriatic arthritis (PsA) is an inflammatory joint disease associated with an increased risk of cardiovascular (CV) events. Apremilast, an oral phosphodiesterase 4 inhibitor (PDE4), has recently been approved for treatment of PsA. PDE4 is one of the major phosphodiesterases expressed in leukocytes. PDE4 inhibition by apremilast elevates cyclic adenosine monophosphate (cAMP) levels in immune cells, which in turn down-regulates the inflammatory response by reducing the expression of pro-inflammatory mediators and increasing the production of anti-inflammatory mediators. In view of these anti-inflammatory effects of apremilast we expect favorable effects on the cardiovascular burden in PsA patients. Body composition, specifically adipose tissue, is likely to play an important role in cardiovascular disease. By investigation the mechanism of apremilast at several levels, e.g. basal metabolic, cholesterol efflux, body composition and plaque size and composition, we can test our hypothesis of apremilast influencing cholesterol efflux, and simultaneously measure the effects of that body composition and on atherosclerosis in the aorta and coronary arteries. This provides us with novel insights in the relation of inflammation and atherosclerosis, and mechanisms in with therapies influence this.

Objectives: The aim of the present study is to identify the association of inflammation in PsA with measures of abdominal fat and cardiometabolic risk factors and evaluate the body composition changes in PsA patients receiving apremilast. Secondly, to assess plaque composition measured by DECT scanning. Thirdly, to evaluate changes in cIMT and cardio-metabolic markers during anti-inflammatory therapy with apremilast.

Single center, longitudinal prospective translational study

Main study parameter/endpoints: Body composition assessed using whole body DXA

Secondary study parameters: Medical history, date of birth, gender, ethnicity, smoking status, use of alcohol, physical activity, date of diagnosis, comorbidity, concomitant medication, use of concomitant and prior DMARDs, height, weight, blood pressure, heart rate, abdominal wall and hip circumference, presence of peripheral arthritis, patient pain VAS, patient global assessment of disease activity (VAS), PASI, LEI, RAPID, ESR, hsCRP, HbA1c (only in patients diagnosed with diabetes mellitus), TC, HDL, LDL, Apo, HDL efflux capacity, glucose, ICAM, VCAM, adiponectines, PCSK9, cIMT, DECT-scan

Onderzoeksopzet

All outcomes will be assessed at baseline, week 26 and week 52

Onderzoeksproduct en/of interventie

None, this is an observational study

Contactpersonen

Publiek

Jan van Breemen Research Institute | Reade
Postbus 58271
M.T. Nurmohamed
Dr. Jan van Breemenstraat 2
Amsterdam 1040 HG
The Netherlands
+31 020 242 1000

Wetenschappelijk

Jan van Breemen Research Institute | Reade
Postbus 58271
M.T. Nurmohamed
Dr. Jan van Breemenstraat 2
Amsterdam 1040 HG
The Netherlands
+31 020 242 1000

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Adult (≥18 years) patients with active PsA

- Indication to start with apremilast (Otezla)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Inability or unwillingness to sign informed consent

- Contraindication for apremilast (i.e. pregnancy and hypersensitivity to apremilast and/or its excipients)

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	18-01-2017
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	16-05-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7023
NTR-old	NTR7222
Ander register	P1655 // NL59047.048.16 : METC Slotervaartziekenhuis en Reade

Resultaten