Apremilast and cardiometabolic effects

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON19880

Source
NTR

Health condition

Psoriatic arthritis (PsA)

Sponsors and support

Primary sponsor: Reade, outpatient rheumatology clinic
Source(s) of monetary or material Support: Celgene

Intervention

Outcome measures

Primary outcome

- 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.

Secondary outcome

- Height, weight, blood pressure, heart rate, abdominal wall and hip circumference

- Presence of peripheral arthritis will be assessed by performing a 68 tender joint count and 66 swollen joint count

- Patient pain, as reported on a visual analogue scale

- Patient global assessment of disease activity as reported on a visual analogue scale

- PASI

- LEI

- RAPID questionnaire

- Laboratory investigations

- Carotid intima media thickness (cIMT)

- Dual energy CT-scanning (DECT-scan), at baseline and week 26, to determine the presence of atherosclerosis and plaque composition in large arteries

Study description

Background summary

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

Study design

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

Intervention

None, this is an observational study

Contacts

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Eligibility criteria

Inclusion criteria

- Adult (≥18 years) patients with active PsA

- Indication to start with apremilast (Otezla)

Exclusion criteria

- Inability or unwillingness to sign informed consent

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

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-01-2017
Enrollment:	50
Type:	Anticipated

Ethics review

Positive opinion

Date:	16-05-2018
Application type:	First submission

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
NTR-new	NL7023
NTR-old	NTR7222
Other	P1655 // NL59047.048.16 : METC Slotervaartziekenhuis en Reade

Study results