A prospective study on the cardio-metabolic effects of apremilast in patients with psoriatic arthritis

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Observational invasive

Summary

ID

NL-OMON43353

Source
ToetsingOnline

Brief title
Aprmilast for psoriatic arthritis

Condition

- Joint disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
inflammatory arthritis, psoriatic arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Reade
Source(s) of monetary or material Support: Celgene,Celgene Corporation

Intervention

Keyword: Apremilast, Atherosclerosis, Body composition, Psoriatic arthritis

Outcome measures

Primary outcome

Body composition assessed using whole body DEXA

Secondary outcome

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 description

Background summary

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.

Study objective

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.

Study design

Single center, longitudinal prospective translational study

Study burden and risks

Participation in scientific research takes patients extra time because of the additional tests being conducted. During study visits, blood will be drawn, which is associated with pain at the needle insertion or a small hematoma after the blood collection.
If patients undergo the DXA scan and the DECT, they are exposed to radiation. The extra radiation received with this study is approximately 10 mSv. The extra radiation is within the standards that apply in our country for this type of additional radiation exposure.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Adult (>=18 years) patients with active psoriatic arthritis
- Starting apremilast

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 invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-03-2017
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	12-10-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-10-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL59047.048.16