A Phase 3, Randomized, Double-Blind, Study Comparing ABT-494 to Placebo in Subjects with Active Psoriatic Arthritis Who Have a History of Inadequate Response to at Least One Biologic Disease Modifying Anti-Rheumatic Drug (bDMARD) - SELECT - PsA 2

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Autoimmune disorders
Study type	Interventional

Summary

ID

NL-OMON45660

Source
ToetsingOnline

Brief title
SELECT-PsA 2

Condition

- Autoimmune disorders

Synonym
Artritis Psoriatica, psoriatic arthritis

Research involving
Human

Sponsors and support

Primary sponsor: AbbVie
Source(s) of monetary or material Support: AbbVie

Intervention

Keyword: Double Blind, JAK-inhibitor, Placebo, Psoriatic Artritis

Outcome measures

Primary outcome

The proportion of subjects achieving ACR20 response

Secondary outcome

1. Change from baseline in HAQ-DI

2. Proportion of subjects achieving a static Investigator Global Assessment

(sIGA) of Psoriasis of 0 or 1 and at least a 2-point improvement from baseline

3. Psoriasis Area Severity Index (PASI) 75 response (for subjects with >= 3% BSA

psoriasis at baseline)

4. Change from baseline in SF-36 PCS

5. Proportion of subjects achieving Minimal Disease Activity (MDA)

6. Change from baseline in FACIT-Fatigue Questionnaire;

7. Change from baseline in Self-Assessment of Psoriasis Symptoms (SAPS)

Questionnaire

8. ACR 50/70 response rate

9. ACR 20 response rate at Week 1

Study description

Background summary

Psoriatic Arthritis (PsA) is a chronic systemic inflammatory disease classified as a subtype of spondyloarthritis (SpA) and characterized by the association of arthritis and psoriasis.
Patients with PsA experience varying combinations of disease manifestations affecting the synovium, tendons, entheses, skin, and bone.
PsA patients require treatment of the entire spectrum of disease manifestations.
Despite the beneficial results achieved with currently available biologic agents, there remains a clear medical need for additional therapeutic options in PsA for patients with inadequate response to or intolerance to currently available therapies.

Study objective

This is a Phase 3 multicenter study that includes two periods. Period 1 is designed to compare the safety, tolerability, and efficacy of upadacitinib low dose once daily (QD) and high dose QD versus placebo in participants with moderately to severely active Psoriatic Arthritis (PsA) who have an inadequate response to Biological Disease Modifying Anti-Rheumatic Drug (bDMARDs). Period 2 evaluates the safety, tolerability and efficacy of upadacitinib low dose QD and high dose QD in subjects with PsA who have completed Period 1.

Study design

A Phase 3, Randomized, Double-Blind, Study Comparing upadacitinib to Placebo in Subjects with Active Psoriatic Arthritis Who Have a History of Inadequate Response to at Least One Biologic Disease Modifying Anti-Rheumatic Drug (DMARD)

Intervention

Each study participant will need to take study drug by mouth once daily (upadacitinib low or high dose, or matching placebo tablets)

Study burden and risks

There is a higher burden for subjects participating in this trial compared to their standard of care. Subject will be
visiting the hospital more frequently. During these visits study procedures will be performed including blood sampling and questionnaires. Subject will also be tested for TB, significant heart conditions, pregnancy, HCV/HBV and HIV. Subjects will also complete a daily diary and questionnaire. Women of childbearing potential should practice a method of birth control, during the

study through at least 30 days after the last dose of study drug. If male, subjects must practice contraception during the study through at least 30 days after last dose of study drug.
Subjects will either receive upadacitinib or placebo during the study. The most common side effects reported during previous studies of upadacitinib were headache, upper chest infection, common cold, back pain, diarrhea and cough. An elevation of an enzyme in the blood called creatine phosphokinase (CPK, a protein released mainly from muscle cells) was observed in treated patients.

Safety monitoring will be done during the study.

Despite the availability of various PsA therapies, many patients still do not respond adequately to these treatments, or gradually lose response over time. There is evidence for clinical benefit of JAK inhibition in PsA based on 2 Phase 3 studies of a different, non-selective JAK inhibitor. The risks and burden associated with participating in this study are acceptable in regards to the potential benefit study subjects could possibly have.

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

1. Male or female, at least 18 years of age
2. Diagnosed with psoriatic arthritis with symptom onset at least 6 months prior to the Screening Visit and fulfillment of the Classification Criteria for PsA (CASPAR)
3. Subject has active disease at Baseline defined as >= 3 tender joints (based on 68 joint counts) and >= 3 swollen joints (based on 66 joint counts) at Screening and Baseline Visits
4. Diagnosis of active plaque psoriasis or documented history of plaque psoriasis
5. Subject has had an inadequate response or an intolerance to treatment with at least 1 bDMARD

Exclusion criteria

1. Prior exposure to any Janus Kinase (JAK) inhibitor
2. Current treatment with > 2 non-biologic DMARDs; or use of DMARDs other than MTX, SSZ, LEF, apremilast, HCQ, bucillamine, or iguratimod; or use of MTX in combination with LEF.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-07-2018
Enrollment:	20
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Upadacitinib
Generic name:	ABT-494

Ethics review

Approved WMO Date:	11-07-2017
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	03-10-2017
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	01-11-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	30-11-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	21-12-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	15-01-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	16-01-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-08-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	27-08-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	07-09-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	19-11-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	14-12-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	20-12-2018
Application type:	Amendment

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	21-12-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	10-04-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-05-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	18-10-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
EudraCT	EUCTR2016-004152-30-NL
ClinicalTrials.gov	NCT03104374
CCMO	NL61362.078.17