A Phase 3b Multicenter, Randomized, Double-Blind, Double-Dummy, Active Controlled
Study Comparing the Safety and Efficacy of Upadacitinib to Dupilumab in Adult Subjects with Moderate to Severe Atopic Dermatitis.

Published: 14-03-2019
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The objective of this study is to evaluate the efficacy and safety of upadacitinib versus dupilumab for the treatment of adult subjects with moderate to severe atopic dermatitis who are candidates for systemic therapy.

Ethical review	Approved WMO
Status	Completed
Health condition type	Epidermal and dermal conditions
Study type	Interventional

Summary

ID

NL-OMON49672

Source
ToetsingOnline

Brief title
M16-046

Condition

- Epidermal and dermal conditions

Synonym
atopic eczema, eczema

Research involving
Human

Sponsors and support

Primary sponsor: Abbvie b.v.
Source(s) of monetary or material Support: AbbVie

Intervention

Keyword: Adults, Atopic Dermatitis, Upadacitinib

Outcome measures

Primary outcome

Proportion of subjects achieving a 75% reduction in Eczema Area Severity Index

(EASI 75) at Week 16

Secondary outcome

1. Percent change from baseline to Week 16 in Worst Pruritus NRS

2. Proportion of subjects achieving EASI 100 from baseline at Week 16

3. Proportion of subjects achieving EASI 90 from baseline at Week 16

4. Percent change from baseline to Week 4 in Worst Pruritus NRS

5. Proportion of subjects achieving EASI 75 from baseline at Week 2

6. Percent change from baseline to Week 1 in Worst Pruritus NRS

Study description

Background summary

Evidence suggests that inhibition of Janus kinase (JAK)-mediated pathways may be a promising approach for the treatment of subjects with moderate to severe atopic dermatitis (AD). Current treatment paradigms for AD suggest that there is a need for additional treatment options for patients. More selective JAK inhibitors may decrease the risk for infection (including viral reactivation) and/or malignancy that are observed with pan JAK inhibitor or less selective

JAK inhibitors. AbbVie is developing a small molecule inhibitor of JAK, upadacitinib, that may address the current needs for subjects with AD.

Study objective

The objective of this study is to evaluate the efficacy and safety of upadacitinib versus dupilumab for the treatment of adult subjects with moderate to severe atopic dermatitis who are candidates for systemic therapy.

Study design

This is a Phase -3, randomized, double-blind, double-dummy, active controlled multicenter study. The study is comprised of a 35-day screening period, a 24 week double-blind treatment period, and a Follow-up Visit after 12 weeks.

Intervention

Subjects will be randomized in a 1:1 ratio and will receive upadacitinib or dupilumab and placebo until Week 24 visit:
• Upadacitinib tablets + placebo pre-filled syringe; OR
• Dupilumab + placebo tablet

Study burden and risks

There will be 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. 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.

Subjects will either receive upadacitinib or dupilumab during the study. The most common side effects reported during previous studies of upadacitinib were headache, upper chest infection, common cold, 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. The majority of these patients did not have any muscle symptoms and did not stop study drug because of elevated CPK levels. The most common side effects that are reported in previous studies with dupilumab are reactions to the skin, and inflammation of the lining of the eye.

The objective of the study is to evaluate the efficacy of upadacitinib when compared to the active treatment dupilumab, with both treatments expected to be well tolerated in adult subjects with moderate to severe AD, indicating that

there is an acceptable rationale to conduct this study. There may or may not be benefit for study subjects but there may be benefit for future patients with atopic dermatitis. The subject*s condition may get better, may worsen, or may stay unchanged.

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

• Male or female subjects 18 between 75 years of age
• Active moderate to severe atopic dermatitis defined by EASI, IGA, BSA, and pruritus
• Candidate for systemic therapy or have recently required systemic therapy for atopic dermatitis

Exclusion criteria

• Prior exposure to any JAK inhibitor
• Unable or unwilling to discontinue current AD treatments prior to the study
• Requirement of prohibited medications during the study
• Other active skin diseases or skin infections requiring systemic treatment or would interfere with appropriate assessment of atopic dermatitis lesions
• Female subject who is pregnant, breastfeeding, or considering pregnancy during the study

Study design

Design

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	12-11-2019
Enrollment:	24
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	dupilumab
Generic name:	Dupixent
Product type:	Medicine
Brand name:	upadacitinib

Generic name:	---
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	14-03-2019
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	19-03-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	04-04-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	05-06-2019
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	08-07-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	15-10-2019
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)
Approved WMO Date:	04-12-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	31-12-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	06-02-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	06-05-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	29-06-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	05-10-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	25-11-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	01-12-2020
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	EUCTR2018-002264-57-NL
ClinicalTrials.gov	NCT03738397
CCMO	NL68247.078.19

Study results

Date completed:	15-10-2020
Results posted:	06-12-2021

URL result
URL
Type
int
Naam
M2.2 Samenvatting voor de leek
URL

Internal documents
File