A Phase 3b/4 Randomized, Open-label, Efficacy Assessor Blinded Study, Comparing the Safety and Assessor Blinded Efficacy of Upadacitinib to Dupilumab in Subjects with Moderate to Severe Atopic Dermatitis (Level-Up)

Published: 15-12-2022
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This study compares upadacitinib to dupilumab in adolescent and adult participants with moderate to severe AD who have inadequate response to systemic therapies. Adverse events and change in the disease activity will be assessed.

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

Summary

ID

NL-OMON53823

Source
ToetsingOnline

Brief title
M23-696

Condition

- Epidermal and dermal conditions

Synonym
Atopic dermatitis, eczema

Research involving

Human

Sponsors and support

Primary sponsor: Site Management & Monitoring
Source(s) of monetary or material Support: AbbVie B.V.

Intervention

Keyword: Atopic dermatitis, Dose escalation, Dupilumab, Upadacitinib

Outcome measures

Primary outcome

Percentage of Participants Achieving both 90% Eczema Area and Severity Index

(EASI 90) and Worst Pruritus Numerical Rating Scale of 0 or 1 (WPNRS 0/1) at

week 16.

Secondary outcome

- Percentage of Participants Achieving an improvement in Worst Pruritus

Numerical Rating Scale (WP-NRS) 4 among those with Baseline WP-NRS

4 at week 16

- Percentage of Participants Achieving a Worst Pruritus Numerical Rating Scale

of 0 or 1 (WP-NRS 0/1) among Participants with Baseline WP-NRS > 1 up to week 16

- Percentage of Participants Achieving 75% of Eczema Area and Severity Index

(EASI 75) at week 2

- Percentage of Participants Achieving 100% of Eczema Area and Severity Index

(EASI 100) at week 16

- Percentage of Participants Achieving at least 90% of Eczema Area and Severity

Index (EASI 90) up tp week 16

Study description

Background summary

Atopic dermatitis (AD) is a skin condition that may cause a rash and itching due to inflammation of the skin. Therapies spread over the skin may not be enough to control the AD in trial participants who require systemic anti-inflammatory treatment.

Study objective

This study compares upadacitinib to dupilumab in adolescent and adult participants with moderate to severe AD who have inadequate response to systemic therapies. Adverse events and change in the disease activity will be assessed.

Study design

Randomized, open label, blinded assessor, parallel group study

Intervention

Participants will receive upadacitinib oral tablets once daily or dupilumab as per its label for 32 weeks and followed for 30 days.

Study burden and risks

There may be higher treatment burden for participants in this trial compared to their standard of care . Participants will attend regular visits during the study at a hospital or clinic. The effect of the treatment will be checked by medical assessments, blood tests, checking for side effects and completing questionnaires.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)

Inclusion criteria

o Subjects must be at least >= 12 years old and <= 64 years old at Screening Visit. Adolescent subjects (between >= 12 and < 18 years of age) may be enrolled only if there is local approval for dupilumab in this age group.
o Body weight must be >= 40 kg at the Baseline Visit for subjects between >= 12 and <=18 years of age, unless there are higher weight requirements per the local approved label for dupilumab, in which case the more restricted requirement must be followed.
o Chronic AD with onset of symptoms at least 3 years prior to baseline and subject meets Hanifin and Rajka criteria
o EASI score >= 16; vIGA-AD score >= 3 and >= 10% BSA of AD involvement at the Baseline Visit;
o Baseline weekly average of daily Worst Pruritus NRS >= 4.
o Documented history of inadequate response to previous systemic treatment defined as documented history of previous inadequate response to at least one prior systemic treatment for AD OR for whom other systemic treatments are otherwise medically inadvisable (e.g., because of important side effects or safety risks).

Exclusion criteria

o Prior exposure to any oral or topical JAK inhibitor (including but not limited to upadacitinib [Rinvoq®], tofacitinib [Xeljanz®], ruxolitinib [Jakafi® or Opzelura®], baricitinib [Olumiant®], peficitinib [Smyraf®], abrocitinib [Cibinqo®], and filgotinib [Jyseleca®]), fedratinib [Inrebic®], and deucravacitinib [Sotyktu*])
o Prior exposure to dupilumab, tralokinumab, or lebrikizumab

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	15-08-2023
Enrollment:	8
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Dupixent
Generic name:	Dupilumab
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Rinvoq

Generic name:	Upadacitinib
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	15-12-2022
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	18-01-2023
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	02-07-2023
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	01-09-2023
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	21-12-2023
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	12-01-2024
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	19-03-2024
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	02-04-2024
Application type:	Amendment

Review commission: METC Brabant (Tilburg)

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	EUCTR2022-002482-15-NL
ClinicalTrials.gov	NCT05601882
CCMO	NL82972.028.22