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A Study of 2 Doses of Ritlecitinib in People 12 Years of Age and Older With Alopecia Areata (ALLEGRO-100)

Pfizer

Status and phase

Not yet enrolling | Phase 3

Conditions

Alopecia Areata

Treatments

Drug: Placebo - 50 mg
Drug: Ritlecitinib 50 mg
Drug: Placebo - 100 mg
Drug: Ritlecitinib 100 mg

Study type

Interventional

Funder types

Industry

Identifiers

NCT06873945
B7981094
2024-519370-40-00 (Registry Identifier)

Take notes

Contact trial

Timeline

Last updated: Mar 13, 2025

Start date
Mar 19, 2025 • 1 day ago

Today
Mar 21, 2025

End date
Mar 09, 2027 • in 1 year and 11 months

Pfizer

Details and patient eligibility

About

The purpose of the study is to learn about the safety and effects of the study medicine (called ritlecitinib) for the treatment of alopecia areata. Alopecia areata is a disease that causes hair loss on the scalp, face, and areas of the body.

Ritlecitinib is approved in many countries at a dose of 50 mg (milligram) taken by mouth once a day for the treatment of patients 12 years and older with severe alopecia areata. This study will look at both the 50 mg dose and a 100 mg dose.

This study is seeking participants who:

- Are 12 years of age or older
- Have a diagnosis of alopecia areata
- Have lost 50% or more of the hair on their scalp
- Do not have any other conditions that causes hair loss
- Are willing to stop all other treatments that they may be taking for alopecia areata

About 550 participants will take part in in this study.

Participants will be chosen by chance, like drawing names out of a hat, to receive 1 of 2 different amounts of ritlecitinib (50 mg and 100 mg) taken by mouth once daily.

The 2 doses of ritlecitinib in this study will be compared to each other and also to data from previous studies. This will help to see if the 100 mg dose of ritlecitinib is safe and effective.

People will be in this study for about 13 months. During the study, participants will need to visit the study site up to 9 times. Participants will undergo various tests and procedures such as:

- alopecia areata assessment,
- physical examinations,
- hearing tests,
- blood tests,
- x-ray,
- ECG (electrocardiogram),
- photographs of the scalp and eyes. Participants will also be asked to complete questionnaires about their alopecia areata.

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Enrollment	**Sex**
550 estimated patients	All
Ages	**Volunteers**
12+ years old	No Healthy Volunteers

1. 18 years of age or older at screening. Adolescents (12 to <18 years of age at screening) are also eligible for this study, but only if permitted by the local IRB/EC and local regulatory health authority (if applicable). Where these approvals have not been granted, only participants 18 years of age and older at screening will be enrolled.

   Disease Characteristics:

2. Must meet the following alopecia areata criteria at both Screening and Baseline:

   1. Have a clinical diagnosis of alopecia areata with no other etiology of hair loss.
   2. ≥50% hair loss of the scalp, as measured by SALT, without evidence of terminal hair regrowth within the previous 6 months.
   3. Current episode of hair loss ≤10 years.

Exclusion criteria

Medical Conditions:

1. Diseases or conditions other than alopecia areata which affect hair loss, including other types of alopecia, other scalp disease that may impact the alopecia areata assessment, or active systemic diseases that may cause hair loss.
2. History of severe allergic or anaphylactoid reaction to any kinase inhibitor or a known allergy/hypersensitivity to any component (including excipients) of the study intervention.
3. Any psychiatric condition including recent or active suicidal ideation or behavior that meets protocol-defined criteria.
4. General Infection History:

   - Have a history of systemic infection requiring hospitalization or parenteral therapy (antimicrobial, antiviral, antiparasitic, antiprotozoal, or antifungal), or as otherwise judged clinically significant by the investigator, within 3 months prior to Day 1.
   - Have active acute or chronic infection requiring treatment with oral antibiotics, antivirals, antiparasitics, antiprotozoals, or antifungals within 4 weeks prior to Day 1. NOTE: participants may be rescreened after the infection resolves.
   - Evidence or history of untreated, currently treated or inadequately treated active or latent infection with Mycobacterium tuberculosis.

5. Specific Viral Infection History:

   - History (single episode) of disseminated herpes zoster or disseminated herpes simplex, or a recurrent (more than one episode of) localized, dermatomal herpes zoster.
   - Infected with hepatitis B or hepatitis C viruses: all participants will undergo screening for hepatitis B and C for eligibility.

6. Other Medical Conditions:

   - Have hearing loss with progression over the previous 5 years, sudden hearing loss, or middle or inner ear disease such as otitis media, cholesteatoma,

malignancy. Chest imaging may be performed up to 12 weeks prior to Screening.
    - Have any malignancies or have a history of malignancies with the exception of adequately treated or excised nonmetastatic basal cell or squamous cell cancer of the skin or cervical carcinoma in situ.
    - Have a history of any lymphoproliferative disorder such as EBV-related lymphoproliferative disorder, history of lymphoma, history of leukemia, or signs and symptoms suggestive of current lymphatic or lymphoid disease.
    - Significant trauma or major surgery within 1 month of the first dose of study drug or considered in imminent need for surgery.
7. Adolescent participants 12 to <18 years of age without one of the following:
    - Documented evidence from a health professional of having received varicella vaccination (2 doses); or
    - Evidence of prior exposure to varicella zoster virus (VZV) based on serological testing (ie, a positive VZV IgG Ab result) at Screening.
8. Any medical or laboratory abnormality that may increase the risk of study participation or, in the investigator's judgment, make the participant inappropriate for the study.

    Prior/Concomitant Therapy:

9. Current or prior use of any prohibited medication(s), vaccine(s), or treatment(s) within the protocol-defined timelines.

    Prior/Concurrent Clinical Study Experience:

10. Previous administration with an investigational drug or vaccine within 8 weeks (or longer as determined by the local requirement) or 5 half-lives (whichever is longer) before the first dose of study intervention in this study. Participation in studies of other investigational products (drug or vaccine) at any time during their participation in this study.

    Diagnostic Assessments:

11. Any exclusionary abnormalities in laboratory values at Screening, as assessed by the study-specific laboratory and, if deemed necessary, confirmed by a single repeat.
12. Screening standard 12-lead ECG that demonstrates clinically relevant abnormalities.

    Other Exclusion Criteria:

13. Investigator site staff directly involved in the conduct of the study and their family members, site staff otherwise supervised by the investigator, and sponsor and sponsor delegate employees directly involved in the conduct of the study and their family members.

Trial design

Primary purpose	Allocation
Treatment	Randomized

550 participants in 4 patient groups

Ritlecitinib 100 mg

Experimental group

Description:
Randomized to Ritlecitinib 100 mg QD for 48 weeks. In addition to the active Ritlecitinib 100 mg capsule, a placebo capsule matching the Ritlecitinib 50 mg capsule will be given in order to maintain the blind.

Treatment:
Drug: Ritlecitinib 100 mg
Drug: Placebo - 50 mg

Ritlecitinib 50 mg

Experimental group

Description:
Randomized to Ritlecitinib 50 mg QD for 24 weeks. Depending on response status at Week 24 (ie, whether the participant has a SALT score of less than or equal to 20), the participant may be re-randomized to Ritlecitinib 50 mg QD or Ritlecitinib 100 mg QD for another 24 weeks.

In addition to the active Ritlecitinib 50 mg capsule, a placebo capsule matching the Ritlecitinib 100 mg capsule will be given in order to maintain the blind.

Treatment:
Drug: Placebo - 100 mg
Drug: Ritlecitinib 50 mg

External Placebo

No intervention group

Description:
This group will be constructed using participant-level data at Week 24 from placebo groups of the appropriately chosen Pfizer clinical studies of Ritlecitinib in participants with alopecia areata. This data will be used for comparison between each Ritlecitinib dose and placebo at Week 24.

As this arm will utilize data from other studies, no participants will be randomized to receive only placebo in this study.

Synthetic Placebo

No intervention group

data will be used for comparison between Ritlecitinib 100 mg and placebo at Week 36.

As this arm will utilize data from other studies, no participants will be randomized to receive only placebo in this study.

Trial contacts and locations 0

There are currently no registered sites for this trial.

Central trial contact

Pfizer CT.gov Call Center

Contact trial

Similar trials

Evaluation of Serum Levels of Interlukin-15 and Interlukin-21 in Patients With...

Sohag University

Not yet enrolling

Alopecia Areata

Sohag, Egypt

Topical Pentoxifylline; Metformin Versus Betamethasone in the Treatment of Alop...

Assiut University

Not yet enrolling

Alopecia Areata

Assiut, Egypt

Not yet enrolling

Alopecia Areata

Assiut, Egypt

Data sourced from clinicaltrials.gov