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Summary of Clinical Trial Results

For Laypersons

A study to learn how effective and easy-to-use a medicine called risankizumab is for patients with moderate to severe plaque psoriasis

Overall Summary

- Psoriasis is a long-term skin disease which causes red, itchy, scaly patches most commonly on the knees, elbows, scalp, and torso (chest, back, abdomen).
- There are many types of psoriasis, but plaque psoriasis is the most common.
- The reason people have psoriasis is unknown, but researchers think it may be linked to the immune system, which works to protect the body from infection.
- This study took place from June 2019 to August 2020 and included 108 adult patients in the United States.
- Study doctors looked at the safety, efficacy (how well treatment worked) of risankizumab given with an auto-injector (a medical device that delivers a specific dose of medicine through a syringe with the push of a button) that is self-administered by patients.
- The main goals of the study were to see if patients' symptoms of psoriasis improved and if the auto-injector was easy to use by patients throughout the study.
- Symptom improvement was based on the Psoriasis Area and Severity Index (PASI) which measures psoriasis areas (lesions) and their redness, thickness, and scaliness, and the static Physician's Global Assessment (sPGA) which also measures the severity of skin lesions.
- 84.3% of patients achieved at least a 75% improvement in the PASI score, 66.7% of patients achieved at least a 90% improvement in PASI score, and 46.3% of patients achieved a 100% improvement in PASI score.
- 81.5% of patients achieved a sPGA score of clear or almost clear (no or limited signs of psoriasis on their body).
- Ease of use was based on patient questionnaires and evaluation by medical professionals who observed the injections.
- 100% of patients successfully self-administered study drug and no hazards were experienced.
- Patients reported high acceptability of using the auto-injector.
- Around 14.8% of patients in the study had side effects. The most common side effects were upper respiratory tract infection (common infection of the lungs, throat, nose), sinus infection (swelling of the sinuses leading to stuffy or runny nose), and nasopharyngitis (common cold).
- The results of this study may be used by researchers to further develop this medicine.
- If you participated in this study and have questions about your individual care, contact the doctor or staff at your study site.

1. General information about the study

1.1. What was the main objective of this study?

Researchers are looking for a better way to treat a skin disease called psoriasis. Skin cells multiply much faster than normal cells in people with psoriasis. This makes the skin develop rough red patches with white scales. The patches can heal and come back again and are most often found on the knees, elbows, scalp, and torso (chest, back, abdomen). Symptoms are different for every patient.

There are many types of psoriasis, but plaque psoriasis is the most common. The exact cause of psoriasis is unknown, but researchers think it may be caused by the body's immune system.

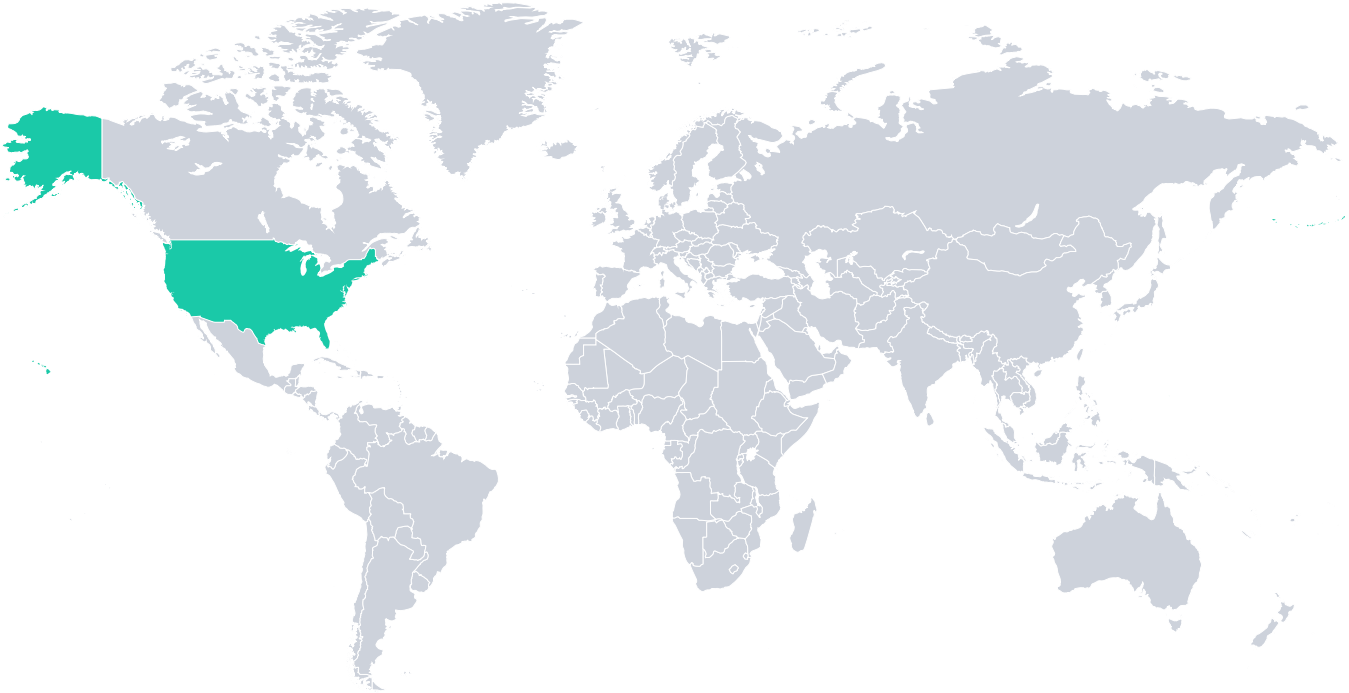
There is no cure for psoriasis, but researchers are looking for a treatment that weakens the activity of the immune system to relieve patients' symptoms. In this study, the benefits and safety of a drug called risankizumab was tested in patients with psoriasis. This study was a Phase 3, open-label study with all patients receiving the same treatment.

- **Phase 3** studies test potential new treatments in a large number of patients with a disease.
- This study was **open-label**, which means that both patients and study doctors knew which medicine/ treatment were given to patients.
- The study also looked for any **side effects** after starting treatment. Side effects are unwanted medical events that were considered by the study doctor to be at least possibly related to treatment.

The main goal of the study was to find out whether treatment with risankizumab in an auto-injector improved psoriasis symptoms and was easy to use.

1.2. When and where was the study done?

This study took place from June 2019 to August 2020 in the United States.

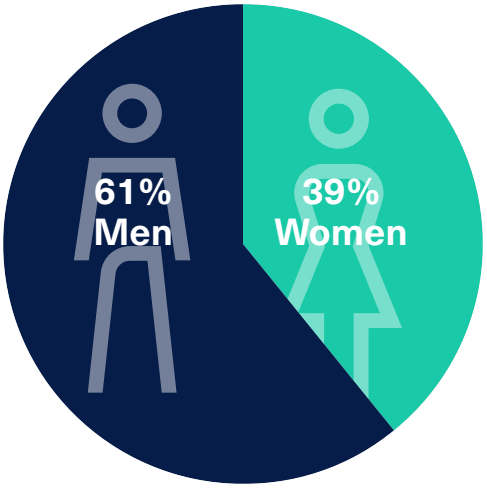


2. What patients were included in this study?

108 adult patients took part in the study. Of the 108 patients, 96 completed the study.

To participate in the study, patients had to have long-lasting moderate to severe plaque psoriasis for at least 6 months. The patient's doctors also needed to agree they were eligible for treatment with systemic therapy (treatment that targets the whole body by circulating through the bloodstream) given as an injection under the skin with a syringe (needle).

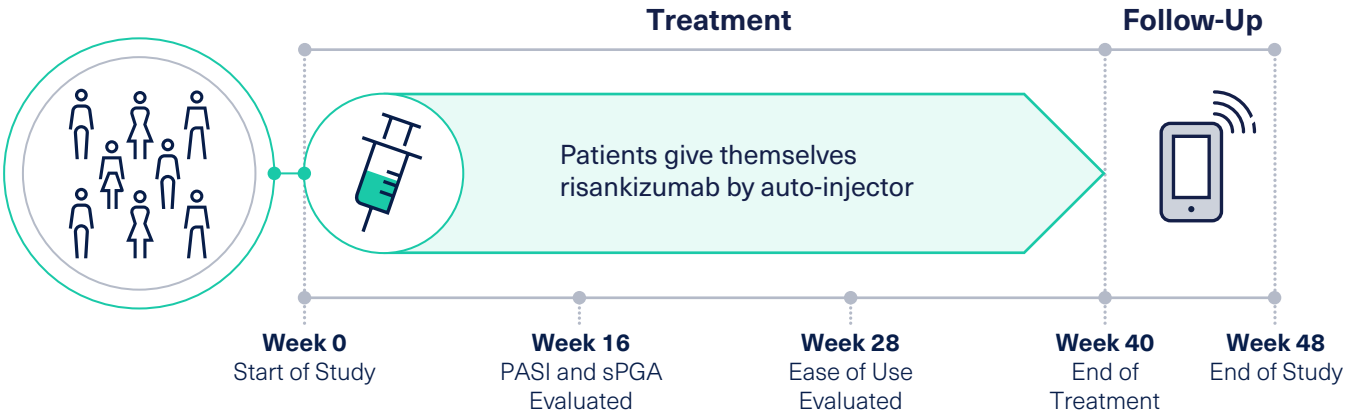
There were more men (61%) than women (39%) in the study. Patient ages ranged from 19 to 78 years of age with an average age of 49 years.



3. Which medicines were studied?

The medicine in this study was called risankizumab. All patients received risankizumab and received training from medical professionals at Week 0 on how to properly self-administer the risankizumab auto-injector. Patients self-administered risankizumab at Weeks 0, 4, 16, and 28.

The diagram below shows how the study was organized.



During the study, patients' psoriasis symptoms were scored using the Psoriasis Area and Severity Index (PASI) and static Physician's Global Assessment (sPGA). PASI is commonly used to measure severity of psoriasis by assessing the amount of the body covered with psoriasis areas (lesions) and their redness, thickness and scaliness. The sPGA also measures the severity of skin lesions but does not factor in the amount of the body affected.

Medical professionals observed the patients using the risankizumab auto-injector and evaluated their ability to use the device without errors. Patients also completed questionnaires before their first dose of risankizumab and after each injection throughout the study and scored their level of comfort with the device.

4. What were the side effects?

Side effects are unwanted medical events that were considered by the study doctor to be at least possibly related to study drug.

A side effect is serious if it leads to death, is life-threatening, puts a patient in the hospital, keeps a patient in the hospital for a long time, or causes a disability that lasts a long time.

- No patient had serious side effects during the study.
- No patient stopped taking the study drug because of side effects during the study.
- No patient died during the study due to side effects/serious side effects.

About 14.8% of patients (16 patients) had side effects during the study. The table below shows information about the common side effects (in at least 2 or more patients) in this study. The most common side effects were upper respiratory tract infection (common infection of the lungs, throat and nose), nasopharyngitis (common cold), and sinus infection (swelling of the sinuses leading to stuffy or runny nose).

	Risankizumab (108 Patients)
Number of patients with at least one side effect	16 (14.8% of patients)
Common Side Effects	
Upper respiratory tract infection	4 (3.7%)
Nasopharyngitis	2 (1.9%)
Sinus infection	2 (1.9%)

5. What were the overall results of the study?

The study was completed as planned. The main goals of the study were to find out if treatment with the risankizumab auto-injector improved psoriasis symptoms and if it was easy to use.

Medical professionals observed the patients using the auto-injector. They found that 100% of patients used the device correctly, delivered the full dose of risankizumab and no patients experienced potential hazards (issues or errors with the auto-injector device) when using the device.

Patients completed questionnaires ranking their levels of comfort and satisfaction using the auto-injector. Scores of 0 meant worst experience ever and scores of 10 meant best experience ever. Patient scores pre-injection and post-injection were high, which demonstrated high patient satisfaction.

Symptom improvement was based on PASI and sPGA scores after 16 weeks of treatment compared to the scores before treatment.

PASI: Most patients had areas of psoriasis that were less severe and/or psoriasis covered smaller areas of their body than before starting treatment.

- 84.3% of patients (91 patients) achieved a 75% or more reduction in their psoriasis symptoms.
- 66.7% of patients (72 patients) achieved a 90% or more reduction in their psoriasis symptoms.
- 46.3% of patients (50 patients) achieved a 100% reduction in their psoriasis symptoms.

sPGA: Most patients had no or limited signs of psoriasis on their body.

- 81.5% of patients (88 patients) had a sPGA score of clear or almost clear.

The number and frequency of side effects were low and similar to those expected in patients with moderate to severe plaque psoriasis.

6. How has the study helped patients and researchers?

This study showed that the risankizumab auto-injector was safe, effective and convenient for patients with moderate to severe plaque psoriasis. In addition, most patients had a reduction in their psoriasis symptoms. The auto-injector was also easy for patients to use and was used correctly.

This summary only shows the results from this study, which may be different from the results of other studies.

7. Are there any plans for future studies?

Multiple risankizumab studies are ongoing for a wide range of conditions.

8. Who sponsored this study?

This study was sponsored by AbbVie. This summary was reviewed for readability by a patient advocacy group.

9. Where can I find out more information about this study?

Title of Study	A Multicenter, Single-Arm, Open Label Study to Assess the Usability of the Risankizumab Autoinjector Combination Product in Adult Patients With Moderate to Severe Plaque Psoriasis
Protocol Number	M16-005
Clinicaltrials.gov	NCT03875508 https://clinicaltrials.gov/ct2/show/NCT03875508?term=M16-005&draw=2&rank=1
Study Sponsor	AbbVie, Inc. Phone: +1 800-633-9110 Email: abbvieclinicaltrials@abbvie.com

Thank You

AbbVie wants to thank all the participants for their time and effort that went into making this study possible.

Clinical study participants help advance science!

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