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Summary of Clinical Trial Results

For Laypersons

A study to learn how effective and safe a medicine containing the study drug risankizumab is compared to placebo (no medicine) to treat adult patients with moderate to severe plaque psoriasis

Overall Summary

- Psoriasis is a skin disorder which causes the skin cells to multiply faster (almost 10 times more) than normal, making the skin look uneven.
- The skin of psoriasis patients can become patchy, red, itchy, and covered with white scales.
- 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 body's immune system.
- Study doctors tested a medicine called risankizumab, which affects the immune system, to treat symptoms of psoriasis.
- This study compared the effects and safety of risankizumab to placebo (no medicine) in adult patients with moderate to severe long-lasting plaque psoriasis.
- The study took place from July 2018 to December 2019 in Russia.
- A total of 50 adult patients took part in this study and 47 completed the study.
- Patients' symptoms were scored after 16 weeks of treatment using the Psoriasis Area and Severity Index (PASI) which measures psoriasis areas (lesions) and their redness, thickness, and scaliness.
- Patients who took risankizumab had greater improvements in their PASI score than patients who took placebo (no medicine).
- Three patients (6.0%) had side effects. The side effects included leukopenia plus neutropenia (a decrease in the number of white blood cells which help fight infection) increased liver enzyme (which may show liver damage), and oral herpes (cold sore on the mouth).
- 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 scalp, knees, elbows, and lower back. Symptoms are different for every patient.

There are many types of psoriasis, but plaque psoriasis is the most common, affecting 2% of the world population. The exact cause of psoriasis is unknown, but researchers think it may be caused by the body's immune system.

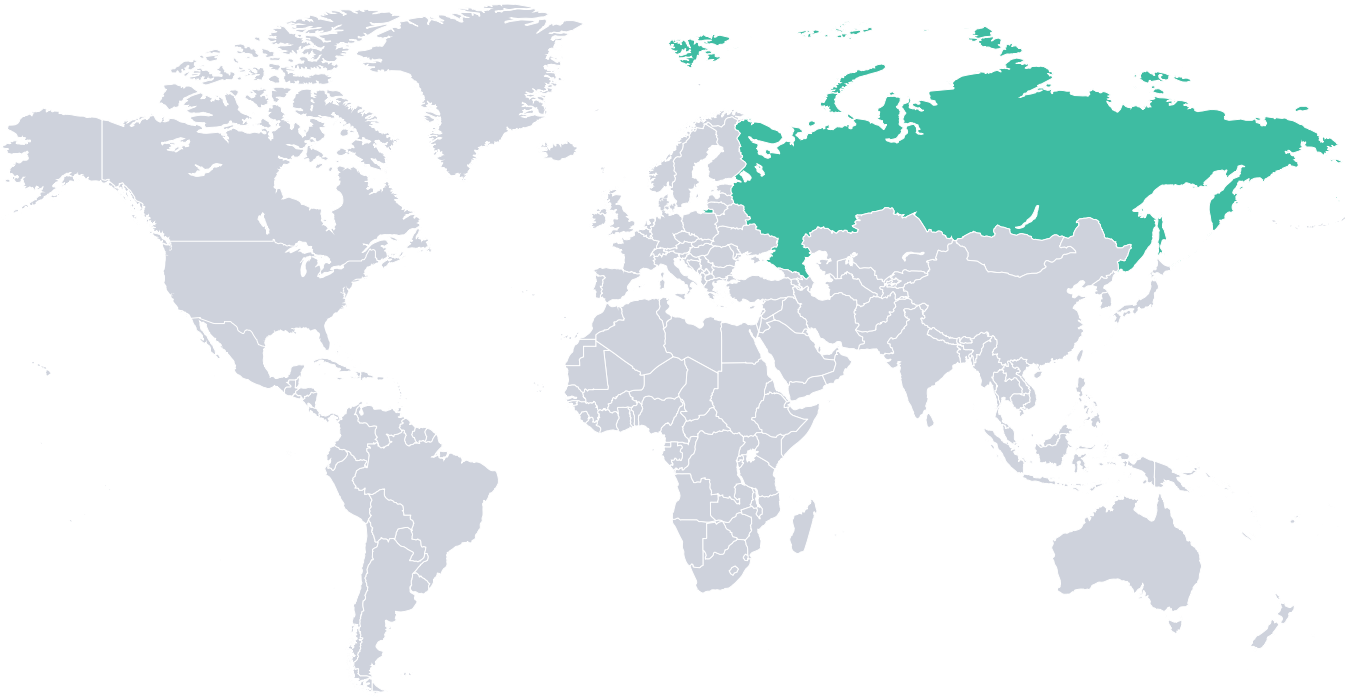
There is no cure for psoriasis, but researchers are looking for a treatment that weakens the activity of the immune system to relieve patients' symptoms. In this study, the benefits and safety of a drug called risankizumab was tested compared to placebo (no medicine) in patients with psoriasis.

This study was a Phase 3 study. Phase 3 studies test potential new treatments in a large number of patients with a disease. The study was also "double-blinded", which means that neither the patients nor the study doctors knew who was given risankizumab and who was given placebo (no medicine).

The main goal of the study was to find out whether treatment with risankizumab improved psoriasis symptoms when compared to placebo. The study also looked for any side effects after starting treatment with risankizumab.

1.2. When and where was the study done?

This study took place from July 2018 to December 2019 in Russia.

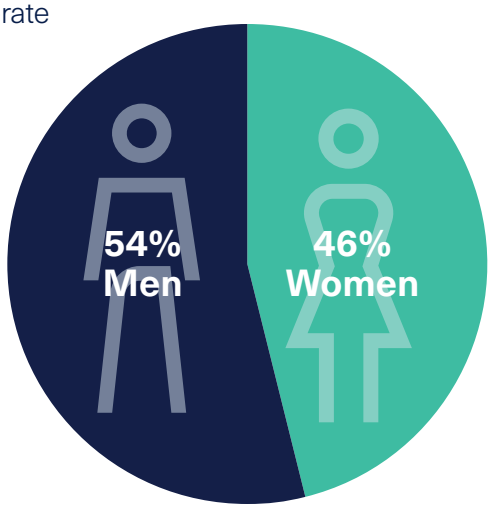


2. What patients were included in this study?

A total of 50 adult patients with psoriasis took part in the study. Of the 50 patients, 47 completed the study.

To participate in the study, patients had to have long-lasting moderate to severe plaque psoriasis, with or without psoriatic arthritis (inflammation of the joints) for at least 6 months.

There were more men (54%) than women (46%) in the study and patient age ranged from 18 to 73 years of age.

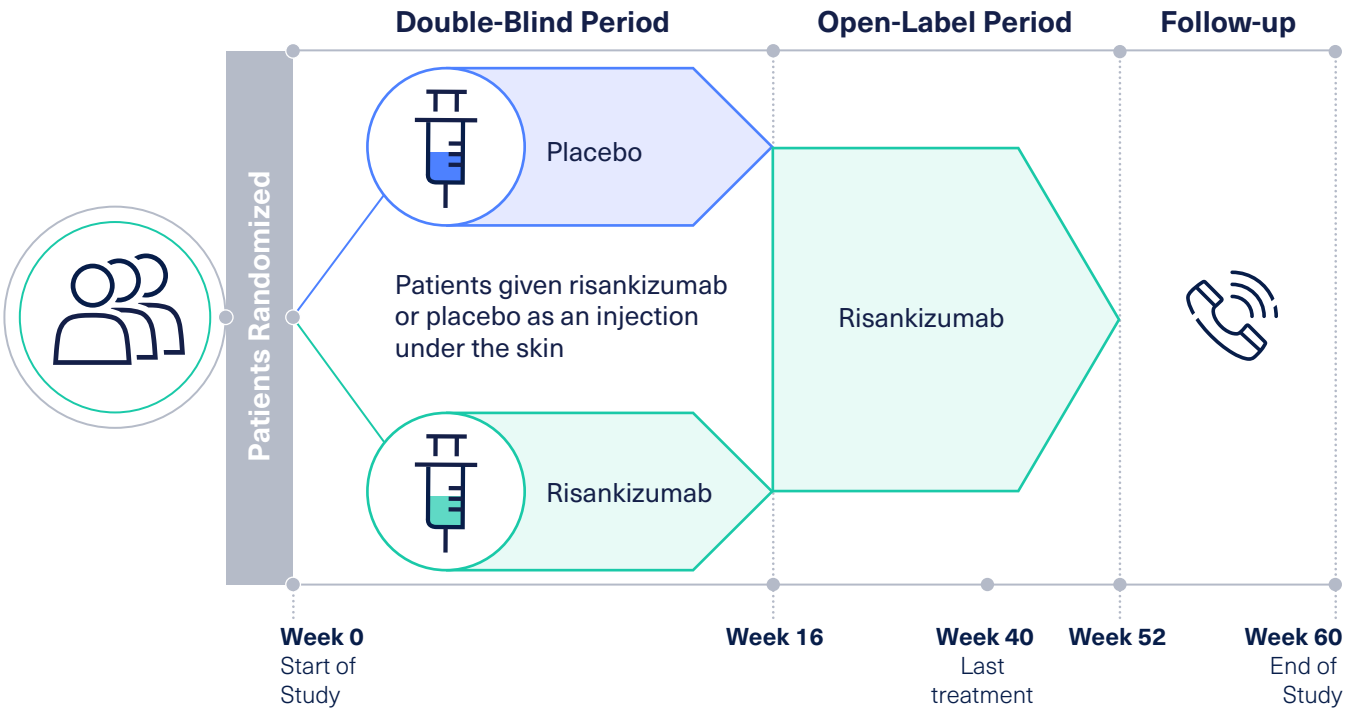


3. Which medicines were studied?

The medicine in this study, called risankizumab, was compared to placebo (no medicine).

The first 16 weeks of the study were “double-blind”, meaning neither the doctor nor the patient knew which patients were given risankizumab and which patients were given placebo. After the “double-blind” period ended, all patients received “open-label” risankizumab for 36 weeks, meaning both patients and doctors knew risankizumab was given.

The diagram below shows how the study was organized.



At the beginning of the study, a computer program was used to randomly (by chance) put the patients into 2 groups with most patients receiving risankizumab. This process is called “randomization”, which helps make the groups similar and reduces the differences in things such as sex and age between the groups. Randomization allows the results of each treatment to be compared as accurately as possible.

During the “double-blind” period, risankizumab or placebo was given as an injection under the skin at Weeks 0 and 4 depending on which group the patient was in. During the “open-label” period, risankizumab was given as an injection under the skin to all patients at Weeks 16, 28, and 40.

4. What were the side effects?

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.

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

No patient had serious side effects during the study.

No patient stopped taking risankizumab because of side effects during the study.

No patient died during the study.

While no patients had serious side effects in this study, about 6.0% of patients (3 patients) had side effects during the study. The table below shows information about the side effects in this study.

Overall Study		
	Placebo followed by risankizumab (9 Patients)	Risankizumab (41 Patients)
Number of patients with at least one side effect	2 (22.2% of patients)	1 (2.4% of patients)
Side Effects	Increased liver enzymes (which may show liver damage), leukopenia plus neutropenia (a decrease in the number of white blood cells which help fight infection)	Oral herpes (cold sore on the mouth)

5. What were the overall results of the study?

The study was completed as planned. The main goal of the study was to find out if treatment with risankizumab improved psoriasis symptoms better than treatment with placebo. Symptom improvement was based on Psoriasis Activity and Severity Index (PASI) scores after 16 weeks of treatment compared to the PASI score before treatment. The PASI score is commonly used to measure the severity of psoriasis.

Study doctors found that patients who took risankizumab had fewer signs of plaque psoriasis at Week 16 compared to patients who took placebo. About 61.0% of patients (25 patients) who took risankizumab and 22.2% of patients (2 patients) who took placebo achieved a 90% or more reduction in their symptoms of psoriasis.

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

6. How has the study helped patients and researchers?

Although this study was limited in its small size of 50 patients, the study showed that risankizumab is safe and effective for patients with plaque psoriasis.

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	Risankizumab Versus Placebo in a Randomized, Double Blind, Parallel Group Trial in Moderate to Severe Plaque Psoriasis to Assess Safety and Efficacy After 16 Weeks of Treatment in the Russian Federation (IMMpress)
Protocol Number	M16-176
Clinicaltrials.gov	NCT03518047 https://clinicaltrials.gov/ct2/show/NCT03518047?term=NCT03518047&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!