

Summary of Clinical Trial Results

For Laypersons



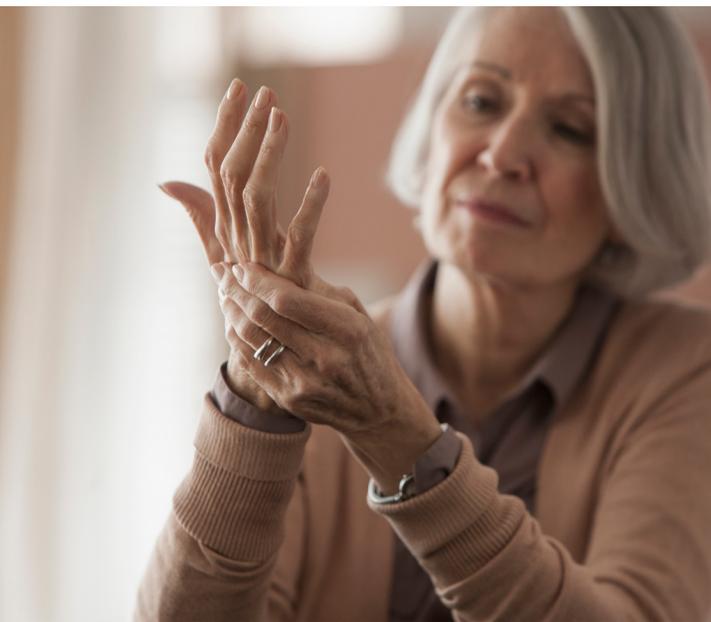
A study to learn how safe and effective a medicine containing the study drug risankizumab is for adult patients with psoriatic arthritis

Overall Summary

- Psoriatic arthritis is a disease that causes pain, stiffness, and swelling of the joints.
- Psoriatic arthritis is long-lasting and can have changes in severity over time. Times of more severe symptoms are called flares.
- The reason people have psoriatic arthritis is unknown, but researchers think it is caused by a mixture of reasons that include genetics, the body's immune system, and outside factors that can trigger the disease.
- In this study, study doctors (investigators) tested a medicine called risankizumab in patients who completed an earlier study with this same medicine.
- In this study, doctors looked at the safety of risankizumab in adult patients with psoriatic arthritis.
- All patients in this study received the same dose of study drug for 36 weeks.
- This study took place from December 2016 to July 2018 in 10 countries.
- Around 60% of patients in the study had side effects. The most common side effect was viral upper respiratory infection (common cold).
- The results of this study will be used by researchers to further develop this medicine.
- If you participated in this study and wish to learn more 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 disease called psoriatic arthritis. Psoriatic arthritis is a long-lasting inflammatory disease that affects 0.3% to 1% of the adult world population. It causes pain, stiffness, and swelling in the joints. The exact cause of psoriatic arthritis is unknown. Researchers think it is caused by a mixture of reasons that include genetics, the body's immune system, and outside factors that may trigger the disease.

There is no cure for psoriatic arthritis, but researchers are looking for a treatment that controls the activity of the immune system to relieve patients' symptoms. The medicines used to treat psoriatic arthritis do not work the same for all patients and symptoms may not improve for some patients despite treatment. Because of this, researchers are looking for different medicines to treat these patients.

Phase 2 studies test potential new treatments in a small number of patients with a condition or disease. This Phase 2 study looked at the benefits and side effects of risankizumab in adult patients with psoriatic arthritis. This study was "open-label" which means that both the patients and study doctors knew patients were given study drug.

The main aim of the study was to find out if the medicine was safe for patients with psoriatic arthritis and if there were any unwanted side effects. This summary only includes the results from this study, which may be different to the results from other studies.

1.2. When and where was the study done?

This study took place from December 2016 to July 2018 in the following countries:

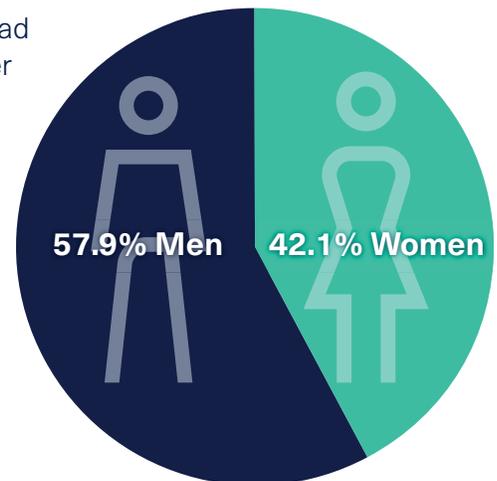


2. What patients were included in this study?

A total of 145 adult patients took part in the study. All the patients had psoriatic arthritis and had completed all treatment visits in an earlier study looking at risankizumab or placebo (no medicine).

Of the 145 patients in this study, 106 completed taking risankizumab and 39 did not: 4 patients left the study because of side effects, 10 patients left the study by personal choice, 1 patient did not return to continue treatment or testing, and 24 patients did not complete the study due to other, unknown reasons.

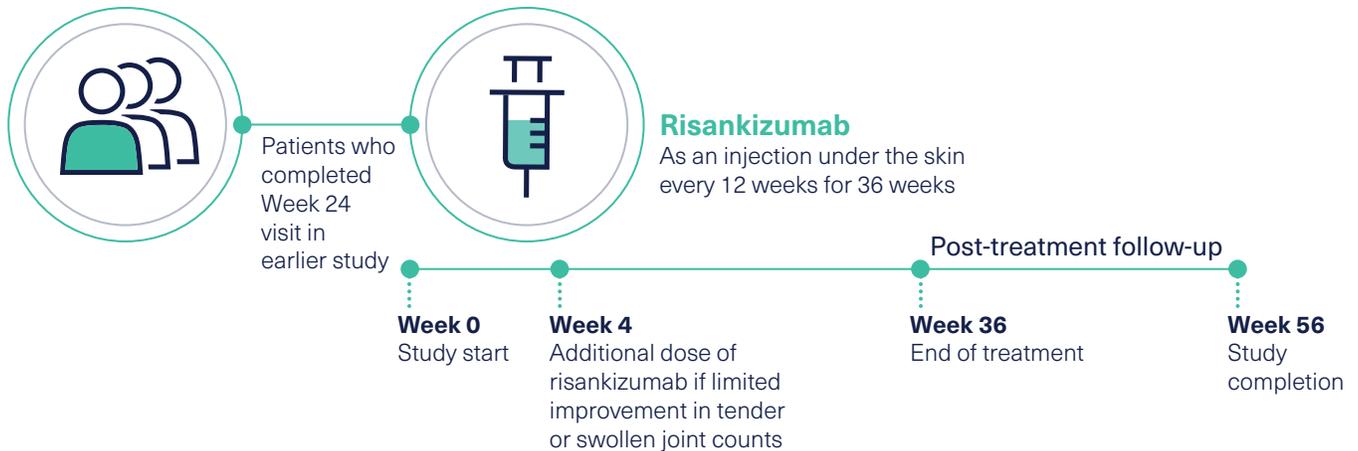
There were more men (57.9%) than women (42.1%) in the study and patients ranged from 21 to 78 years of age.



3. Which medicines were studied?

The medicine in this study was called risankizumab. Study doctors tested one dose of the medicine on all patients in the study given as an injection under the skin at the start of the study and then every twelve weeks for up to 36 weeks. Patients could get an extra dose of study drug as an injection under the skin at week 4 if they did not have an improvement in their tender and swollen joint count after the first 4 weeks of treatment.

The diagram below shows how the study was organized.



At the beginning of the study, all the patients were put into 1 group. The study doctors made sure that each patient had finished treatment in an earlier study with risankizumab or placebo for their psoriatic arthritis and were in good health.

In this study, patients were given the study drug every 12 weeks. If the patients did not respond to the study drug after 4 weeks, the study doctors gave them another dose of the study drug. Both the patients and study doctors knew what study drug and dose the patients were given.

4. What were the side effects?

Side effects are unwanted medical events that happen during a study. They may or may not be caused by the treatment in the study.

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.

Related side effects are side effects that were considered by the study doctor to be at least possibly related to study drug.

About 3.4% of patients (5 patients) had serious side effects during the study. The total number of patients that had serious side effects considered possibly related to the study drug was 0.7% (1 patient).

About 3.4% of patients (5 patients) stopped taking the study drug because of side effects during the study. The total number of patients that stopped taking the study drug because of side effects considered possibly related to the study drug was 0.7% of patients (1 patient; urosepsis). Other reasons for stopping study drug included patient decision and worsening of psoriatic arthritis symptoms.

No patient died during the study.

The table below shows information about the related serious side effects patients had in the study, as well as related side effects patients had that led to the patient stopping study drug, and related side effects leading to death.

	Risankizumab (n=145)
Number of patients with related serious side effects	1 (0.7% of patients)
Related Serious Side Effects	
• Urosepsis (infection caused by an infection of the urinary tract that gets into the bloodstream)	1 (0.7% of patients)
Number of patients who stopped taking study drug because of related side effects	1 (0.7% of patients)
Number of related side effects leading to death	0 (0% of patients)

About 60% of patients (87 patients) had side effects during the study. The total number of patients that had side effects considered possibly related to the study drug was 15.2% (22 patients).

The table below shows information about the common related side effects (in at least 2 or more patients) in this study. The most common related side effect was bronchitis (an infection of the lining of the bronchial tubes which carries air to and from the lungs).

	Risankizumab (n=145)
Number of patients with at least one related side effect	34 (23.4% of patients)
Common Related Side Effects (Related Side effects occurring in at least 2 or more patients)	
• Infections (bronchitis, common cold, sore throat)	13 (9.0% of patients)
• Injection site reactions	3 (2.1% of patients)
• Abnormal blood test (increased liver enzyme test that may show damage to the liver)	2 (1.4% of patients)
• Tissue disorders (worsening of psoriatic arthritis symptoms)	2 (1.4% of patients)

5. What were the overall results of the study?

The study was completed as planned. The study doctors found that the study drug was safe for patients to take for treatment of psoriatic arthritis symptoms. About 60% of patients had side effects, but most were mild and did not lead to stopping study drug.

6. How has the study helped patients and researchers?

The study has helped researchers learn more about the safety of risankizumab as a treatment of psoriatic arthritis. Findings from this study may be used to help develop other studies to learn whether patients with psoriatic arthritis are helped by risankizumab.

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

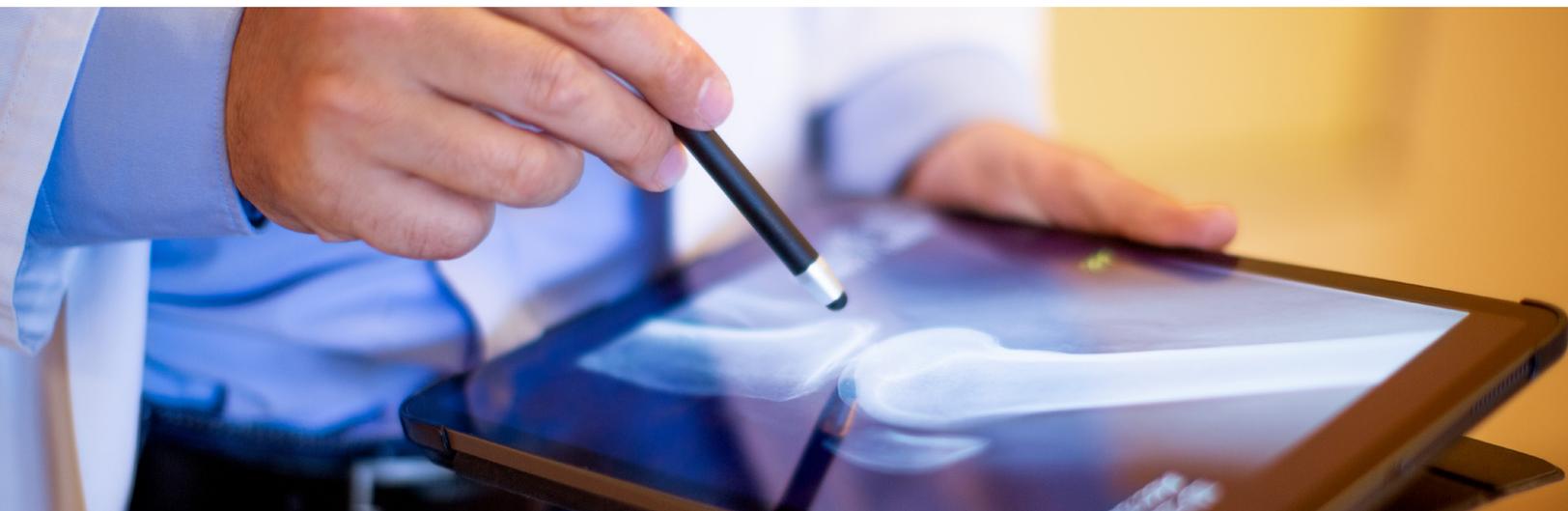
Patients should consult their physicians and/or study doctors with further questions about their individual care and should not make changes in their treatment based on the results of a single study.

7. Are there any plans for future studies?

There are future studies of risankizumab planned for patients with psoriatic arthritis.

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 Phase 2 Single-Arm Open-Label Extension Study to Investigate Safety with Risankizumab in Psoriatic Arthritis Subjects Who Have Completed Week 24 Visit of Study M16-002 (1311.5)
Protocol Number	M16-244
Clinicaltrials.gov	NCT02986373 https://clinicaltrials.gov/ct2/show/NCT02986373?term=M16-244&draw=2&rank=1
EudraCT	2016-003113-94 https://www.clinicaltrialsregister.eu/ctr-search/search?query=2016-003113-94
Study Sponsor	AbbVie Inc Phone: (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!

