

Summary of Clinical Trial Results

For Laypersons



A study to learn how effective and safe a medicine containing the study drug risankizumab compared to secukinumab is for 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 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.
- This study took place from May 2018 to July 2020 in 9 countries.
- Study doctors compared the safety and efficacy (how well treatment worked) of a medicine called risankizumab, to standard treatment with secukinumab.
- A total of 327 adult patients took part in the study and 285 completed the study.
- Patients were placed into 2 groups by chance using a computer program. One group was given risankizumab and the other was given secukinumab.
- Patients' symptoms of psoriasis were scored after 16 and 52 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 secukinumab in this study.
- 29.9% of patients (49 patients) given risankizumab and 28.2% of patients (46 patients) given secukinumab had side effects. The most common side effects were common cold (nasopharyngitis), upper respiratory tract infection, and tiredness (fatigue).
- 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.

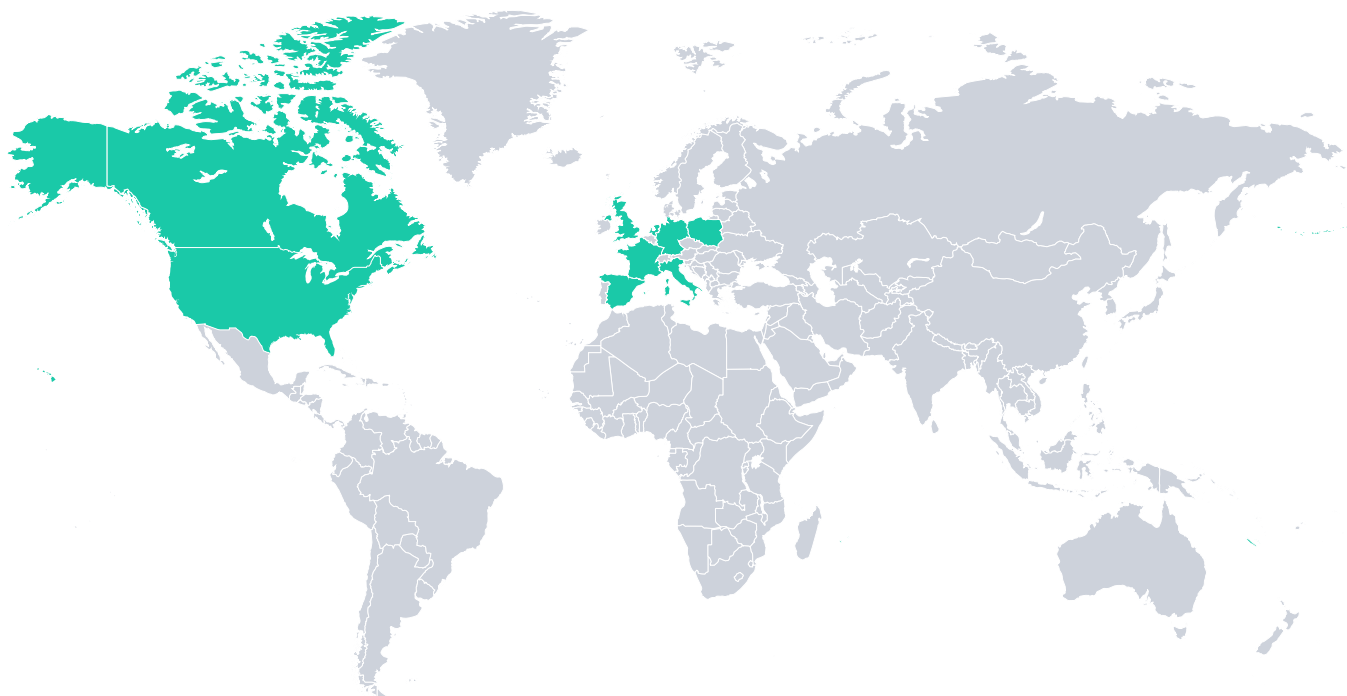
There is no cure for psoriasis, but researchers are looking for treatments that weaken the activity of the immune system to relieve patients' symptoms. In this study, the benefits and safety of a drug called risankizumab was tested compared to standard treatment with secukinumab in patients with psoriasis.

This study was a Phase 3, "open-label" study. Phase 3 studies test potential new treatments in a large number of patients with a disease. "Open-label" means that both patients and the study doctors knew which medicine was given to patients. A computer program was used to randomly (by chance) put patients into 1 of 2 groups. This process is called "randomization" which helps to reduce differences between the groups of patients that are being compared. Randomization allows the results of each treatment to be compared as accurately as possible.

The main goal of the study was to find out whether treatment with risankizumab further improved psoriasis symptoms when compared to treatment with secukinumab. 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 risankizumab or secukinumab.

1.2. When and where was the study done?

This study took place from May 2018 to July 2020 in the following countries: Canada, France, Germany, Italy, the Netherlands, Poland, Spain, the United Kingdom, and the United States.

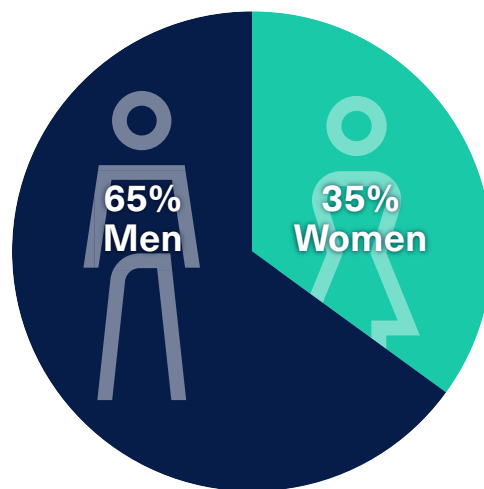


2. What patients were included in this study?

327 adult patients with psoriasis took part in the study.
Of the 327 patients, 285 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. The patients' doctors agreed they were eligible for treatment with systemic therapy (treatment that targets the whole body by circulating through the bloodstream).

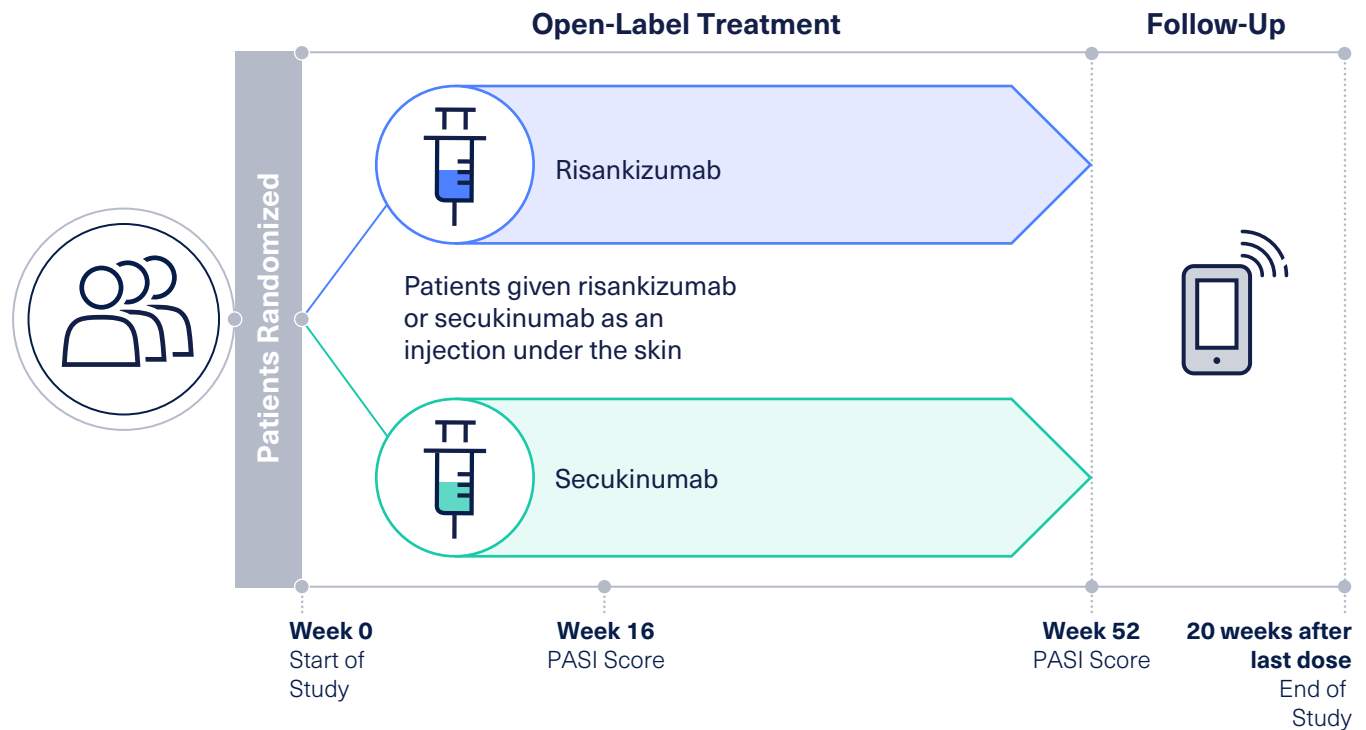
There were more men (65%) than women (35%) in the study. Patient ages ranged from 19 to 87 years of age with an average age of 47 years.



3. Which medicines were studied?

The medicines in this study were called risankizumab and secukinumab. Patients were randomly placed into two groups by a computer to receive “open-label” treatment with either risankizumab or secukinumab given as an injection under the skin.

The diagram below shows how the study was organized.



After 16 weeks and 52 weeks of treatment, patients’ signs and symptoms of psoriasis were scored using the Psoriasis Area and Severity Index (PASI) which measures psoriasis areas (lesions) and their redness, thickness, and scaliness. The PASI score is commonly used to measure severity of psoriasis in clinical studies.

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.

1 patient (0.6% of patients) treated with risankizumab and 1 patient (0.6% of patients) treated with secukinumab had serious side effects during the study.

No patient treated with risankizumab and 3 patients (1.8% of patients) treated with secukinumab stopped taking the study drug because of side effects during the study.

No patient treated with risankizumab or secukinumab died during the study.

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

	Risankizumab (164 Patients)	Secukinumab (163 Patients)
Number of patients with serious side effects	1 (0.6% of patients)	1 (0.6% of patients)
Serious Side Effects		
• Ulcerative colitis (inflammation and sores in the digestive tract)	0 (0.0%)	1 (0.6%)
• Urinary tract infection	1 (0.6%)	0 (0.0%)
Number of patients who stopped taking study drug because of side effects	0 (0.0%)	3 (1.8%)
Reasons for stopping	None	Chest tightness, lack of energy (lethargy), throat tightness, rash, joint pain (arthralgia), ulcerative colitis

29.9% of patients (49 patients) treated with risankizumab and 28.2% of patients (46 patients) had side effects during the study. The table below shows information about the common side effects (in at least 3 or more patients) in either group. The most common side effects in either group were common cold (nasopharyngitis), upper respiratory tract infection, and tiredness (fatigue).

	Risankizumab (164 Patients)	Secukinumab (163 Patients)
Number of patients with at least one side effect	49 (29.9% of patients)	46 (28.2% of patients)
Common Side Effects		
Common cold	11 (6.7%)	8 (4.9%)
Upper respiratory tract infection	9 (5.5%)	7 (4.3%)
Tiredness	4 (2.4%)	2 (1.2%)
Injection site pain	3 (1.8%)	2 (1.2%)
Headache	3 (1.8%)	2 (1.2%)
Oral candidiasis (infection of the mouth caused by a fungus)	2 (1.2%)	3 (1.8%)
Weight increased	3 (1.8%)	1 (0.6%)
Joint pain	3 (1.8%)	1 (0.6%)
Rhinitis (stuffy, runny nose)	3 (1.8%)	0 (0.0%)
Cough	1 (0.6%)	3 (1.8%)

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 more than treatment with secukinumab. Symptom improvement was based on PASI scores after 16 and 52 weeks of treatment compared to the PASI score before treatment.

Study doctors found that patients who took risankizumab had fewer signs and symptoms at Week 16 and Week 52 compared to patients who took secukinumab.

Week 16: 73.8% of patients (121 patients) who took risankizumab and 65.6% of patients (107 patients) who took secukinumab achieved a 90% or more reduction in their symptoms of psoriasis.

Week 52: 86.6% of patients (142 patients) who took risankizumab and 57.1% of patients (93 patients) who took secukinumab achieved a 90% or more reduction in their symptoms of psoriasis.

The number and frequency of side effects were similar in both treatment groups 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 risankizumab is safe and effective for patients with plaque psoriasis and provides greater improvement in psoriasis signs and symptoms when compared to secukinumab.

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, Randomized, Open Label, Efficacy Assessor-Blinded Study of Risankizumab Compared to Secukinumab for the Treatment of Adult Subjects With Moderate to Severe Plaque Psoriasis Who Are Candidates for Systemic Therapy
Protocol Number	M16-766
Clinicaltrials.gov	NCT03478787 https://clinicaltrials.gov/ct2/show/NCT03478787?term=M16-766&draw=2&rank=1
EudraCT	2017-004932-12 https://www.clinicaltrialsregister.eu/ctr-search/search?query=2017-004932-12
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!

