

# Summary of Clinical Trial Results

For Laypersons



**A study to learn how safe a medicine containing the study drug risankizumab is for patients with moderate to severe Crohn's disease.**

## Overall Summary

- Crohn's disease (CD) is a long-lasting disease of the bowel that causes inflammation of any part of the gastrointestinal tract.
- Symptoms vary from person to person and can have changes in severity over time. Increases in severity are called flares.
- The reason people have Crohn's disease is unknown, but researchers think it is caused by a mixture of reasons that include genetics and the body's immune system.
- In this study, study doctors (investigators) tested a medicine called risankizumab, which affects the immune system, to treat symptoms of Crohn's disease.
- The main aim of the study was to find out if risankizumab was safe for Crohn's disease patients to take for a long time.
- 65 adults participated in the study and all patients received risankizumab.
- The study took place from September 2015 to June 2019 in 9 countries.
- Around 92.3% of patients in the study had side effects.
- The most common side effects were nasopharyngitis (common cold), gastroenteritis (infectious diarrhea), fatigue (overall feeling of tiredness or lack of energy), abdominal pain, CD, arthralgia (joint pain), and nausea.
- The study was ended early by the study sponsor (AbbVie) so patients could join another long-term study of the safety of risankizumab in patients with Crohn's disease.
- The results of this study will be used by researchers to further develop this medicine.
- If you participated in this study and wish to discuss your individual care, contact the doctor or staff at your study site.

# 1. General information about the study

## 1.1. Why was this study done?



Researchers are looking for a better way to treat Crohn's disease. Crohn's disease is an inflammatory bowel disease which can cause many different symptoms including stomach pain, diarrhea, tiredness, and weight loss. Symptoms are different for every patient.

The medicines used to treat Crohn's disease do not work the same for all patients. Symptoms do not improve for some patients receiving treatment. Because of this, researchers are looking for different medicines to treat the disease.

The study doctors in this study used a medicine called risankizumab. Risankizumab works to control the activity of the immune system to help patients with inflammatory diseases, like Crohn's disease.

The main aim of the study was to find out if risankizumab was safe for patients to take for a long time and if there were any unwanted side effects.

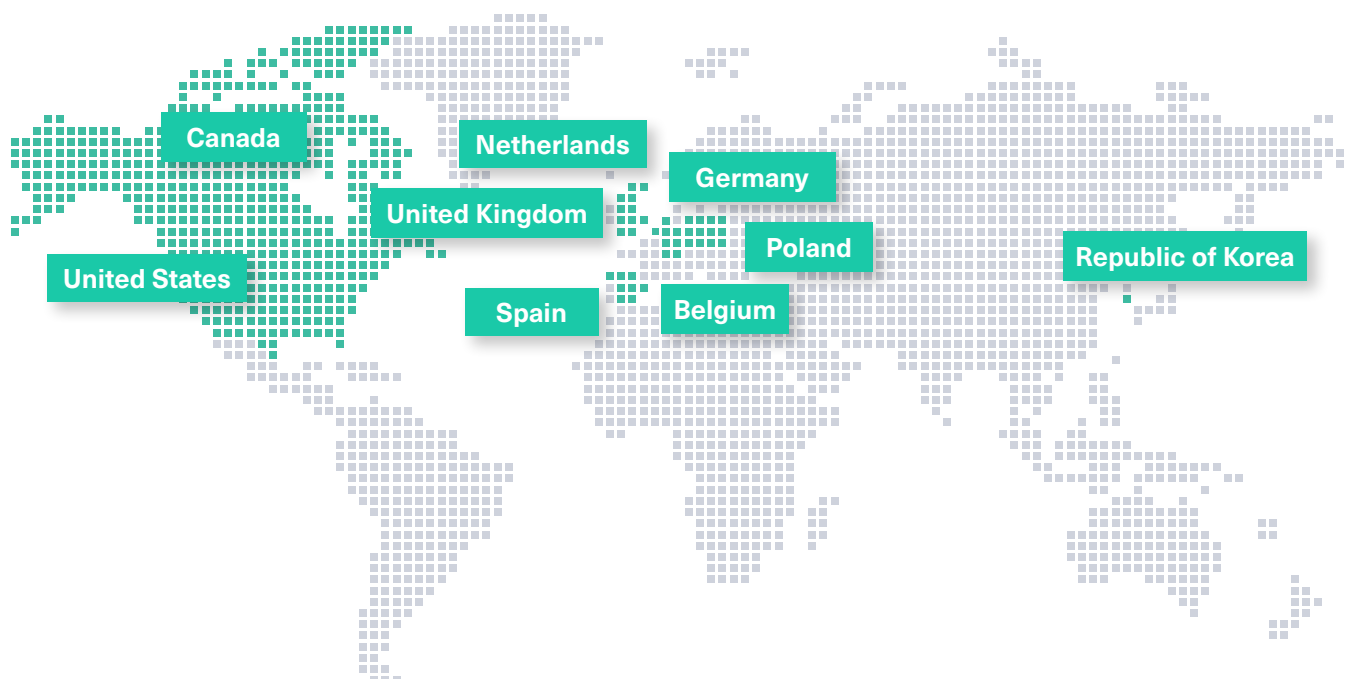
Researchers have tested this medicine in many studies of people with different inflammatory diseases, including Crohn's disease. Phase 2 studies test treatments in a small number of patients.

In this phase 2 study, the study doctors looked at the safety of risankizumab in patients who had responded well to risankizumab in an earlier study, showing less symptoms of the disease with treatment. This study was also "open-label", which means that both the patient and the study doctors knew which treatments were given.

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

## 1.2. When and where was the study done?

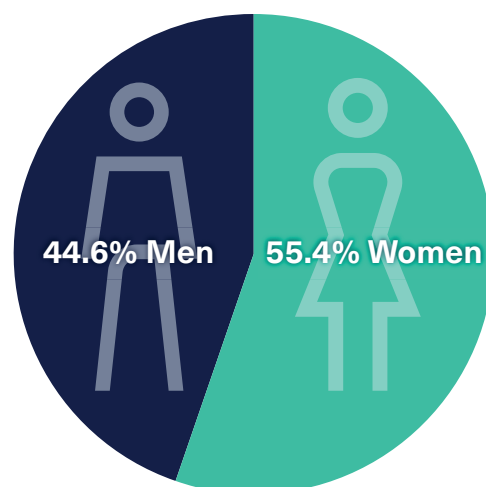
This study took place from September 2015 to June 2019 in the following countries



## 2. What patients were included in this study?

A total of 65 adult patients took part in the study. All patients had moderate to severe Crohn's disease, had received risankizumab in an earlier study, and achieved clinical remission of Crohn's disease. Clinical remission was based on patient-reported information (symptoms and quality of life) and medical information (laboratory values, medication use). Of the 65 patients, 44 completed the study and 21 did not: 4 patients left the study by personal choice, 7 did not complete the study due to side effects, and 10 patients did not complete the study due to other reasons.

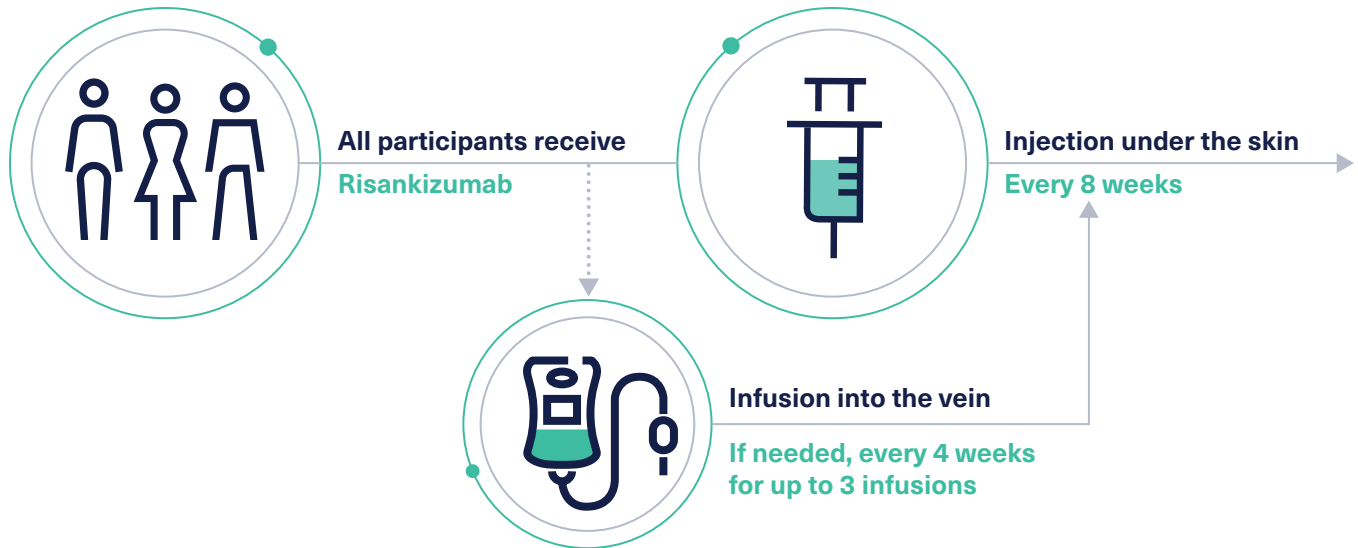
There were more women (55.4%) than men (44.6%) in the study. For participation in this study, study doctors selected only adult patients and ages ranged from 19 to 67 years.



### 3. Which medicines were studied?

The medicine in this study was risankizumab. Most patients were given risankizumab as an injection under the skin every 8 weeks, but a small number of patients were given risankizumab as an infusion into the vein every 4 weeks before receiving risankizumab as an injection under the skin.

The diagram below shows how the study was organized.



At the beginning of the study, all patients were put into one group. The study doctors made sure that patients had responded well to risankizumab in an earlier study. At the end of this study, patients could join another risankizumab study looking at the long-term safety of the medicine in patients with Crohn's disease.

## 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 participant in the hospital, keeps a participant 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 35.4% of patients (23 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 4.6% (3 patients).

About 9.2% of patients (6 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 1.5% of patients (1 patient).

No patient died during the study and no cancers were reported.

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

Risankizumab (n=65)	
<b>Number of patients with related serious side effects</b>	3 (4.6% of patients)
<b>Related Serious Side Effects</b>	
• Ileal stenosis (blockage of any part of the intestine)	1 (1.5% of patients)
• Partial bowel obstruction (blockage of part of the bowel)	1 (1.5% of patients)
• Termination of pregnancy due to fetal abnormality	1 (1.5% of patients)
<b>Number of patients who stopped taking study drug because of related side effects</b>	1 (1.5% of patients)
• Reasons for stopping	Side effects, patient decision, other reasons
<b>Number of related side effects leading to death</b>	0 (0% of patients)

About 92.3% of patients (60 patients) had side effects during the study. The total number of patients that had side effects considered possibly related to the study drug was 40% (26 patients).

The table below shows information about the common related side effects (in at least 4% of patients) in this study. The most common related side effects were nasopharyngitis (common cold), fatigue, injection site redness, and injection site pain.

Risankizumab (n=65)	
Number of patients with at least one related side effect	26 (40% of patients)
<b>Common Related Side Effects</b> (Related side effects occurring in at least 4% of patients)	
• Nasopharyngitis (common cold)	6 (9.2% of patients)
• Fatigue	3 (4.6% of patients)
• Injection site pain	3 (4.6% of patients)
• Injection site redness	3 (4.6% of patients)

## 5. What were the overall results of the study?

The study doctors found that risankizumab was generally safe and well-tolerated in this study. Most patients did have side effects, but most were mild or moderate and they did not cause patients to stop taking risankizumab.

The study was ended early by the sponsor to allow patients to join another risankizumab study looking at the long-term safety of the medicine in patients with Crohn's disease. Of the 44 patients who completed this study, all chose to continue in the other study.

## 6. How has the study helped patients and researchers?

The study helped researchers learn more about the safety of risankizumab as a treatment of Crohn's disease. This study was ended early to allow patients to join another risankizumab study in this patient population.

This summary only shows the results from this study, which may be different from the results of other studies with risankizumab in patients with Crohn's disease.

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 ongoing studies of risankizumab in this patient population, including another risankizumab study looking at the long-term safety of the medicine in patients with Crohn's disease.



## 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	An Open Label, Single Group, Long Term Safety Extension Trial of BI655066/ ABBV-066 (Risankizumab), in Patients With Moderately to Severely Active Crohn's Disease
Protocol Number	M15-989
Clinicaltrials.gov	NCT02513459 <a href="https://clinicaltrials.gov/ct2/show/NCT02513459?term=M15-989&amp;draw=2&amp;rank=2">https://clinicaltrials.gov/ct2/show/NCT02513459?term=M15-989&amp;draw=2&amp;rank=2</a>
EudraCT	2016-003191-50 <a href="https://www.clinicaltrialsregister.eu/ctr-search/search?query=M15-989">https://www.clinicaltrialsregister.eu/ctr-search/search?query=M15-989</a>
Study Sponsor	AbbVie Inc Phone: (800) 633-9110 Email: <a href="mailto:abbvieclinicaltrials@abbvie.com">abbvieclinicaltrials@abbvie.com</a>

## 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!

