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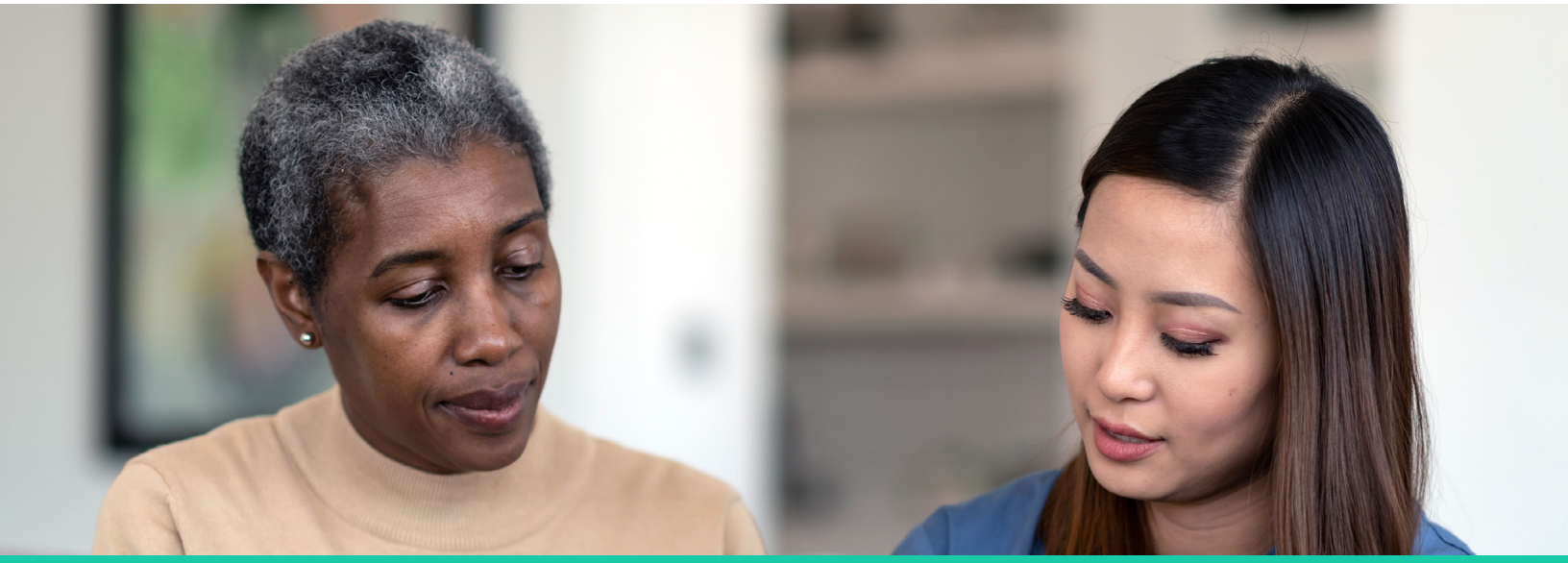
Summary of Clinical Trial Results

For Laypersons



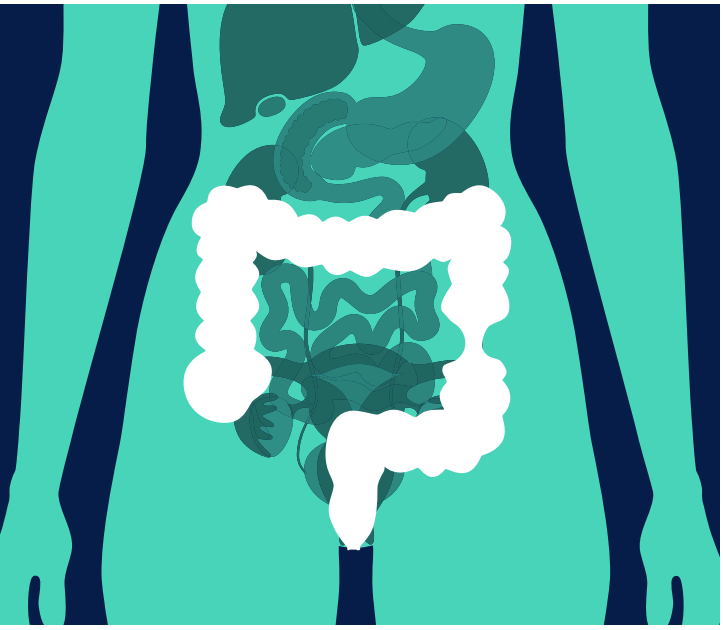
A study to learn how effective and safe a medicine called eluxadoline works to treat patients with irritable bowel syndrome with diarrhea, who may also have bile acid malabsorption

Overall Summary

- Irritable bowel syndrome (IBS) is one of the most common disorders of the digestive system, affecting between 10–15% of the world's population.
- The main goal of this study was to learn more about how safe and effective eluxadoline was for the treatment of patients with irritable bowel syndrome with diarrhea (IBS-D) with and without bile acid malabsorption (BAM).
- A total of 24 adult patients with IBS-D took part in the study, all of which completed the study.
- Patients were assigned to 1 of 2 groups; the first group included patients with IBS-D with signs of BAM. The second group included patients with IBS-D without signs of BAM.
- About 83.3% of IBS-D patients with BAM (10 patients) and 58.3% of IBS-D patients without BAM (7 patients) had side effects during the study. The most common side effects were abdominal pain and passing gas.
- This study showed that after treatment with eluxadoline, IBS-D patients with and without BAM saw similar improvements in Bristol Stool Form Scale (BSFS) scores.
- 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?



Irritable bowel syndrome is one of the most common disorders of the digestive system, affecting between 10–15% of the world's population. Symptoms of IBS include bloating, diarrhea, abdominal pain, and constipation. There is no cure for IBS; however, there are treatments available to help reduce symptoms.

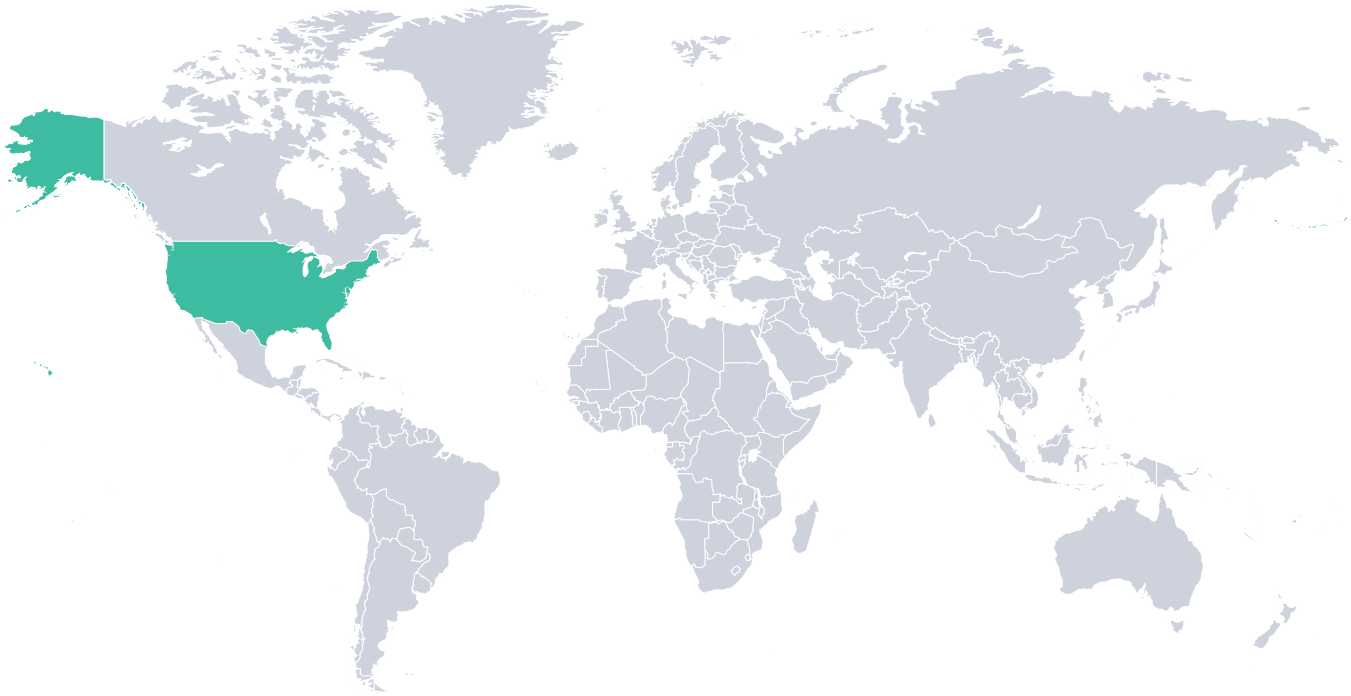
Researchers in this study used a medicine called eluxadoline. Eluxadoline works on part of the digestive system to help patients with a condition called IBS-D. IBS-D is a subtype of IBS that causes increased diarrhea. Researchers have tested eluxadoline in many studies of people with IBS-D, and eluxadoline has been approved to treat IBS-D in adults.

The main goal of this study was to learn more about how safe and effective eluxadoline was for the treatment of IBS-D patients with and without BAM. BAM is a condition wherein a digestive fluid called bile acid collects in the colon. This increases the amount of water and salts in the colon, leading to symptoms such as watery diarrhea and loss of control of bowel movements (passing poop). Researchers wanted to know if the effectiveness of eluxadoline may be different in IBS-D patients with and without BAM, as symptoms of IBS-D and BAM closely overlap. Researchers planned this study as a Phase 4, open-label study.

- **Phase 4 studies** test treatments that have already been approved to treat patients with a condition or disease. In this Phase 4 study, the study doctors tested the benefits of eluxadoline in patients with IBS-D with and without BAM. The study doctors also looked for any side effects patients may have had after treatment with eluxadoline. A side effect is a medical event considered by the study doctors to be at least possibly related to study drug/treatment.
- This study was "**open-label**", which means that both patients and study doctors knew which medicine was given to patients.

1.2. When and where was the study done?

This study took place from February 2018 to April 2020 in the United States.



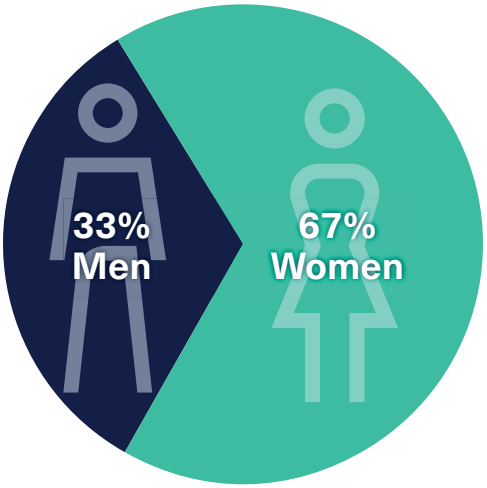
2. What patients were included in this study?

A total of 24 adult patients with IBS-D took part in the study, all of which completed the study.

There were more women (67%) than men (33%) in the study. Patients ranged from 21 to 69 years of age. The average age of patients was 40.9 years.

To participate in this study, patients had to have been diagnosed with IBS-D with or without BAM.

Patients could not participate if they had been diagnosed with irritable bowel syndrome with constipation (IBS-C), mixed IBS, or a different type of IBS.



3. Which medicines were studied?

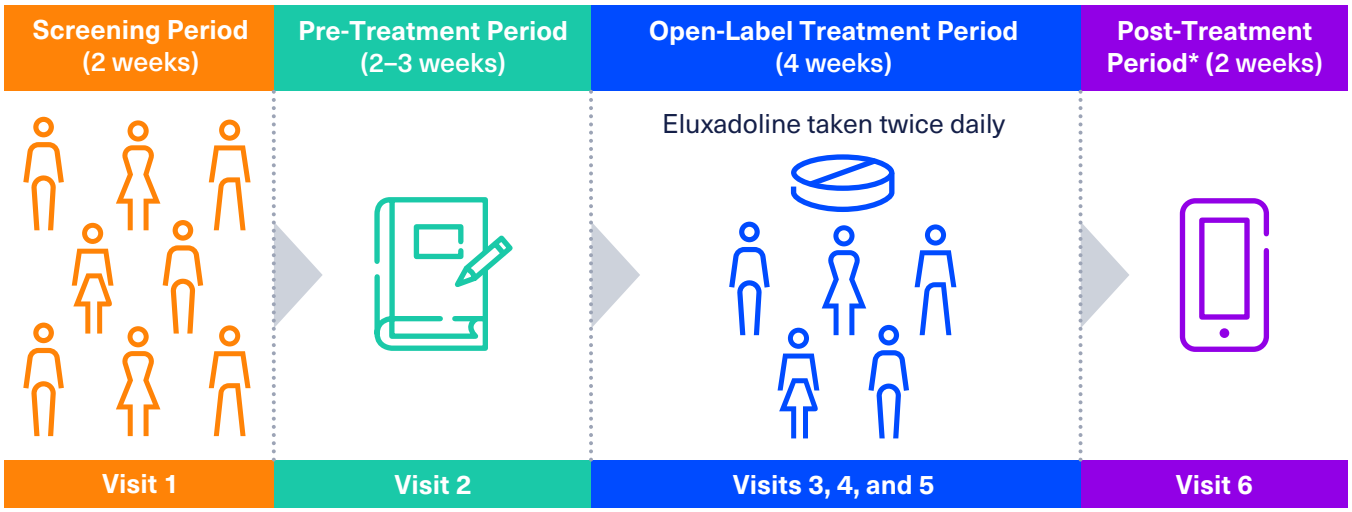
The medicine in this study was called eluxadoline. The study was split into 4 parts: Screening Period, Pre-Treatment Period, Open-Label Treatment Period, and a Post-Treatment Period.

During the Screening Period, the study doctors selected patients who met all the requirements of the planned study.

In the Pre-Treatment Period, patients were given instructions on how to complete their electronic diary during the Open-Label Treatment Period. Patients recorded symptoms such as abdominal pain, bloating, and bowel movements. Patients must have completed an electronic diary of their symptoms at least 10 of the 14 days prior to the start of the study.

In the Open-Label Treatment Period, patients were assigned to 1 of 2 groups. The first group included patients with IBS-D with signs of BAM. The second group included patients with IBS-D without signs of BAM. The groups were matched as closely as possible by age, gender, and symptom severity. Study doctors tested the same dose of eluxadoline in both groups. Eluxadoline was given as tablets for the patients to swallow twice a day with food.

During the Post-Treatment Period, patients were contacted again by study doctors after getting their last dose of eluxadoline. The diagram below shows how the study was organized.



*Patients could attend this visit in person or via telephone call

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 study drug.

No patients had serious side effects during the study.

No patients stopped taking the study drug because of side effects during the study.

No patients died during the study.

About 83.3% of IBS-D patients with BAM (10 patients) and 58.3% of IBS-D patients without BAM (7 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) in this study. The most common side effects were abdominal pain and passing gas.

Overall Study		
	IBS-D patients with BAM (12 Patients)	IBS-D patients without BAM (12 Patients)
Number of patients with at least one side effect	10 (83.3% of patients)	7 (58.3% of patients)
• Abdominal pain	6 (50.0%)	1 (8.3%)
• Passing gas	2 (16.7%)	4 (33.3%)
• Abdominal swelling	2 (16.7%)	3 (25.0%)
• Nausea	3 (25.0%)	1 (8.3%)

Across the whole study, IBS-D patients with BAM experienced more side effects than IBS-D patients without BAM. As shown in the table above, the number and frequency of side effects were similar to those expected in patients who have been treated with eluxadoline for IBS-D.

5. What were the overall results of the study?

The study was completed as planned.

One of the main goals of this study was to see if eluxadoline was effective for IBS-D patients with and without BAM. Based on study visits and electronic diary entries, patient's stool (poop) was measured on a scale called the Bristol Stool Form Scale (BSFS). The scale ranged from 1 (separate hard lumps) to 7 (watery). The study doctors found that improvement in BSFS score was similar in both groups of patients.

Another main goal of the study was to evaluate the safety of eluxadoline and to see how patients tolerated the side effects. Therefore, study doctors measured the percentage of patients who experienced at least 1 medical event while participating in the study. These events may or may not be considered by the study doctor to be related to the study drug. In this study, 91.7% of IBS-D patients with BAM (11 patients) and 58.3% of IBS-D patients without BAM (7 patients) had at least one medical event during the study.

In this study, all patients had their laboratory values, vital signs (body temperature, pulse rate, breathing rate, blood pressure), and overall physical conditions monitored. Significant changes in laboratory values, vital signs, and general physical conditions were infrequent and/or small and there were no significant differences in the findings between the IBS-D patients with BAM or without BAM.

6. How has the study helped patients and researchers?

The study has helped researchers to learn more about the safety and effectiveness of eluxadoline for the treatment of patients with IBS-D with and without BAM. It showed that IBS-D patients with and without BAM saw similar improvements in BSFS scores during the study. Overall, significant changes in laboratory test levels, vital signs, and general physical conditions were infrequent and/or small, and occurred at a similar rate in IBS-D patients with and without BAM. The number and frequency of side effects were similar to those expected in patients who have been treated with eluxadoline for IBS-D.

This study was limited as only a smaller number of patients took part. Therefore, generalizing the results from this study for the larger patient population may not be appropriate. This summary only shows the results from this study, which may be different from the results of other studies. Findings from this study may be used in other studies to learn whether patients are helped by eluxadoline.

7. Are there any plans for future studies?

Additional studies of eluxadoline in pediatric patients are ongoing and planned.

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 Pilot Study of Eluxadoline in Participants With Irritable Bowel Syndrome With Diarrhea (IBS-D) Who Have Evidence of Bile Acid Malabsorption (BAM)
Protocol Number	3030-401-002
Clinicaltrials.gov	NCT03441581 https://clinicaltrials.gov/ct2/show/NCT03441581
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!