

Summary of Clinical Trial Results

For Laypersons



A study to learn about the effect and safety of a medicine called atogepant in the treatment of adult patients with migraine

Overall Summary

- A migraine is typically a moderate or severe headache occurring on one side of the head. A migraine attack is a headache that is often accompanied by nausea, vomiting, extreme sensitivity to light and sound, and other symptoms.
- Researchers in this study wanted to know whether a new drug called atogepant could help prevent migraine attacks.
- This study took place from December 2018 to June 2020 in the United States.
- The study was divided into 3 periods: Screening Period, Double-Blind Treatment Period, and Safety Follow-up Period.
- The main goal of this study was to find out if atogepant was safe and effective compared to placebo (no real medicine) in the prevention of migraine attacks.
- The study doctors found that the patients who received atogepant had fewer migraine days on average compared to those who received placebo during the 12-week Double-Blind Treatment Period.
- Patients who received higher doses of atogepant did not necessarily suffer from more side effects than patients who received lower doses of atogepant.
- 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 prevent a medical condition called migraine.

- **A migraine** is typically a moderate or severe headache occurring on one side of the head. A migraine attack is a headache that is often accompanied by nausea, vomiting, extreme sensitivity to light and sound, and other symptoms. The exact cause of migraine is unknown; however, researchers think it is caused by abnormal changes in brain activity.

In this study, doctors wanted to know whether a new drug called atogepant could help prevent migraine attacks. During a migraine attack, a protein is released and may cause pain and inflammation in the body. Atogepant acts by blocking this protein to prevent the migraine attack. Atogepant has been tested in previous studies and has been found to reduce monthly migraine days.

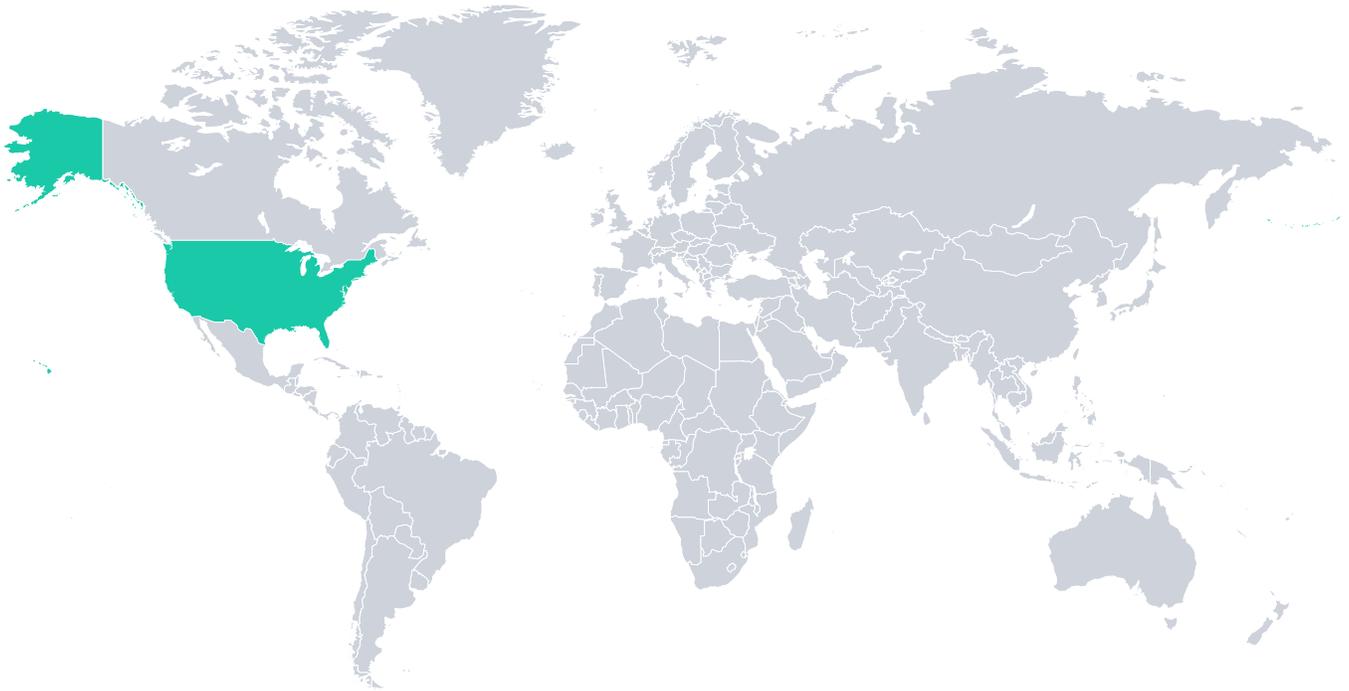
The main goal of this study was to find out if atogepant was safe and effective compared to placebo for the prevention of migraine attacks. Placebo looks like the treatment but has no medicine in it.

This study was planned as a Phase 3, randomized, and double-blind study.

- **Phase 3 studies** test potential new treatments in a large number of patients with a condition or disease. In this Phase 3 study, the study doctors looked at the safety and effectiveness of treatment with atogepant compared to placebo. The study doctors also looked for any side effects patients may have had after treatment with the study drug.
- A **side effect** is a medical event considered by the study doctors to be at least possibly related to the study drug/treatment.
- This study was **double-blinded**, which means that neither the patients nor the study doctors knew who was given which study drug/treatment. This ensures that no study results were influenced.
- This study was also **randomized**, which means a computer program was used to randomly (by chance) put the patients into 1 of 4 groups. This process is called randomization, which helps make the groups similar and reduces the differences between the groups. Randomization allows the results of each treatment to be compared as accurately as possible.

1.2. When and where was the study done?

This study took place from December 2018 to June 2020 in the United States.



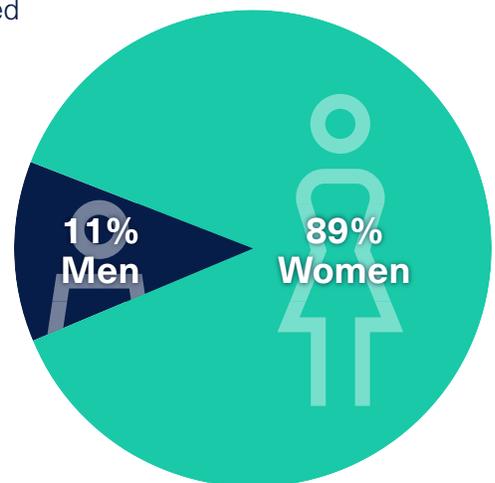
2. What patients were included in this study?

A total of 910 patients took part in the study; of these, 805 completed the study.

More women (89%) than men (11%) participated in the study, as migraine is more common in women. Patients ranged from 18 to 73 years of age, with an average age of 41.6 years.

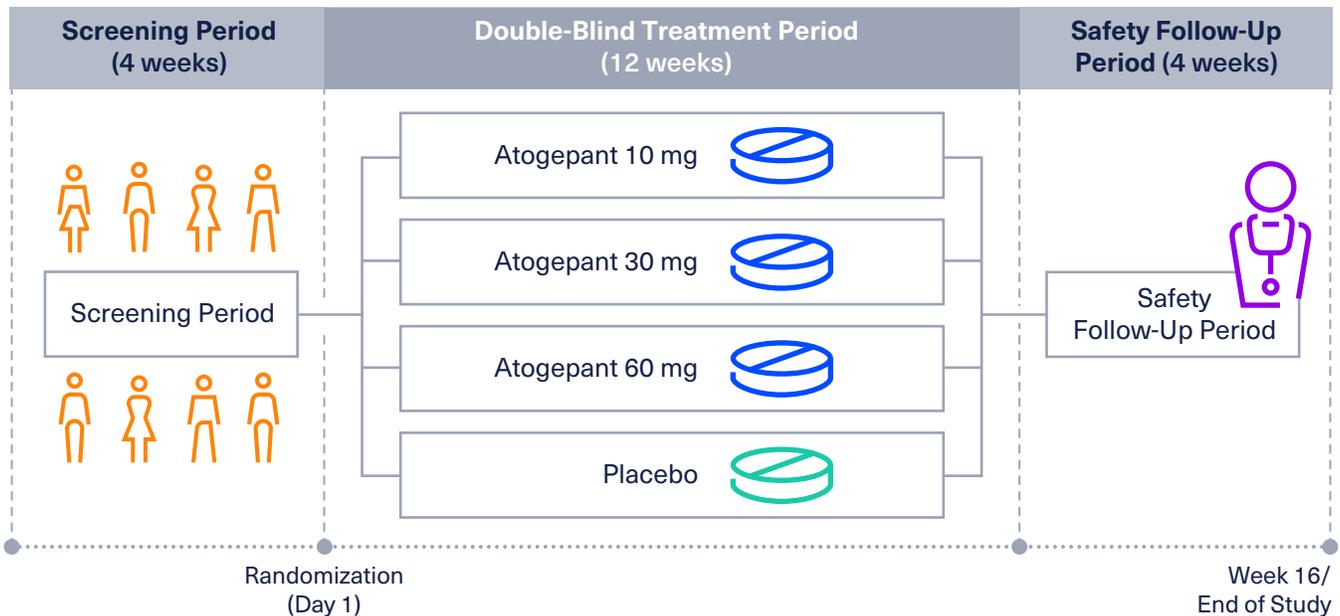
To participate in the study, patients must have had at least a one-year history of migraine with or without aura. A migraine with aura is when a person experiences sensory changes, such as flashes of light, blind spots, or tingling, before the headache part of the migraine attack starts.

Patients must have also experienced 4 to 14 migraine days in the 28 days prior to the study.



3. Which medicines were studied?

The medicine in this study was called atogepant. Study doctors tested different doses of atogepant (10 mg, 30 mg, or 60 mg taken by mouth) and compared them to placebo (no real medicine). The diagram below shows how the study was organized.



The study was divided into 3 periods: Screening Period, Double-Blind Treatment Period, and Safety Follow-Up Period.

- **Screening Period** – Before the study started, a 4-week Screening Period took place to check if patients could join the study. Once the patients were screened, a computer program was used to randomly (by chance) put patients into 1 of 4 treatment groups.
- **Double-Blind Treatment Period** – Patients took atogepant 10 mg, 30 mg, or 60 mg or placebo every day up to 12 weeks. Atogepant was given as a tablet. Patients who received placebo also received tablets, but these did not contain any medicine. Neither the patients nor the study doctors knew which treatment was given to patients.
- **Safety Follow-Up Period** – Patients were followed for 4 weeks after getting the last dose of medicine.

Patients who completed the study may have been eligible to enroll in another migraine study where they could continue to receive treatment with atogepant.

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 the 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 in the atogepant 10 mg group had a serious side effect during the study.
- About 3.2% of patients (7 patients) who received atogepant 10 mg, 1.8% of patients (4 patients) who received atogepant 30 mg, 1.7% of patients (4 patients) who received atogepant 60 mg, and 1.4% of patients (3 patients) who received placebo stopped taking their study drug because of side effects.
- No patients died during the study.

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

| Overall Study | | | | |
|--|---|---|---|---|
| | Placebo (222 Patients) | Atogepant 10 mg (221 Patients) | Atogepant 30 mg (228 Patients) | Atogepant 60 mg (231 Patients) |
| Number of patients with serious side effects | 0 (0.0% of patients) | 1 (0.5% of patients) | 0 (0% of patients) | 0 (0% of patients) |
| Serious Side Effects | | | | |
| • Inflammation of the optic nerve | 0 (0.0%) | 1 (0.5%) | 0 (0.0%) | 0 (0.0%) |
| Number of patients who stopped taking study drug because of side effects | 3 (1.4%) | 7 (3.2%) | 4 (1.8%) | 4 (1.7%) |
| Reasons for stopping | Abdominal pain, migraine, and suicidal thoughts | Abnormal dreams, constipation, headache, inflammation of the optic nerve, itchy, bumpy rash, nausea, tiredness, and vertigo | Constipation, bipolar disorder, and dizziness | Agitation, constipation, decreased appetite, ear pain, difficulty falling and/or staying asleep, excessive sweating, itchiness, nausea, tiredness, and rash |

About 23.1% of patients (51 patients) who received atogepant 10 mg, 14.9% of patients (34 patients) who received atogepant 30 mg, 19.5% of patients (45 patients) who received atogepant 60 mg, and 9.0% of patients (20 patients) who received placebo had side effects during the study.

The table below shows information about the common side effects (in at least 5 or more patients) in this study. The most common side effects were constipation and nausea.

| Overall Study | | | | |
|--|---------------------------|--------------------------------------|--------------------------------------|--------------------------------------|
| | Placebo (222 Patients) | Atogepant 10 mg (221 Patients) | Atogepant 30 mg (228 Patients) | Atogepant 60 mg (231 Patients) |
| Number of patients with at least one side effect | 20 (9.0% of patients) | 51 (23.1% of patients) | 34 (14.9% of patients) | 45 (19.5% of patients) |
| Common Side Effects | | | | |
| Constipation | 1 (0.5%) | 13 (5.9%) | 10 (4.4%) | 12 (5.2%) |
| Nausea | 1 (0.5%) | 7 (3.2%) | 5 (2.2%) | 10 (4.3%) |
| Tiredness | 1 (0.5%) | 3 (1.4%) | 4 (1.8%) | 5 (2.2%) |
| Sleepiness | 2 (0.9%) | 6 (2.7%) | 3 (1.3%) | 3 (1.3%) |

5. What were the overall results of the study?

The study was completed as planned. The study doctors found that the patients who received atogepant had fewer migraine days on average compared to those who received placebo during the 12-week Double-Blind Treatment Period. Also, patients who received atogepant 60 mg showed a greater reduction of migraine days on average compared to patients who received atogepant 30 mg and atogepant 10 mg.

Patients who received higher doses of atogepant did not report more side effects than patients who received lower doses of atogepant.

6. How has the study helped patients and researchers?

The results of this study found that atogepant was safe and effective in the treatment of adult patients with migraine, with or without aura. Patients who received atogepant experienced fewer migraine days on average than patients who received placebo.

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 atogepant.



7. Are there any plans for future studies?

There are several ongoing studies with atogepant and the possibility for future studies.

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 3, Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel group Study to Evaluate the Efficacy, Safety, and Tolerability of Oral Atogepant for the Prevention of Migraine in Participants With Episodic Migraine (Advance) |
| Protocol Number | 3101-301-002 |
| Clinicaltrials.gov | NCT03777059 https://clinicaltrials.gov/ct2/show/NCT03777059?term=NCT03777059&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!

