

# Summary of Clinical Trial Results

For Laypersons



**A study to learn how effective and safe a medicine called bimatoprost works to treat adult patients with open-angle glaucoma or ocular hypertension**

## Overall Summary

- Researchers are looking for a better way to treat open-angle glaucoma and ocular (eye) hypertension.
- The main goal of the study was to learn how safe and effective two different doses of bimatoprost sustained release (SR) were compared to treatment with timolol, an approved drug for lowering eye pressure, to see which treatment was most effective in lowering eye pressure in patients with open-angle glaucoma or ocular hypertension.
- Bimatoprost SR works to provide long-term control of lowered eye pressure, and does not require patients to take a daily medication.
- This study took place from December 2014 to July 2020 in 15 countries.
- A total of 528 patients took part in the study; 472 completed the study and 56 did not.
- This study was split into 4 periods: the Screening Period, Washout Period, Treatment Period, and Extended Follow-Up.
- About 61.9% of patients (109 patients) in the bimatoprost SR higher dose group, 48.0% of patients (84 patients) in the bimatoprost SR lower dose group, and 20.8% of patients (36 patients) in the timolol group had side effects during the study.
- Patients who received bimatoprost SR (lower or higher dose) saw at least as much improvement in reduced eye pressure when compared to patients who received timolol.
- 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

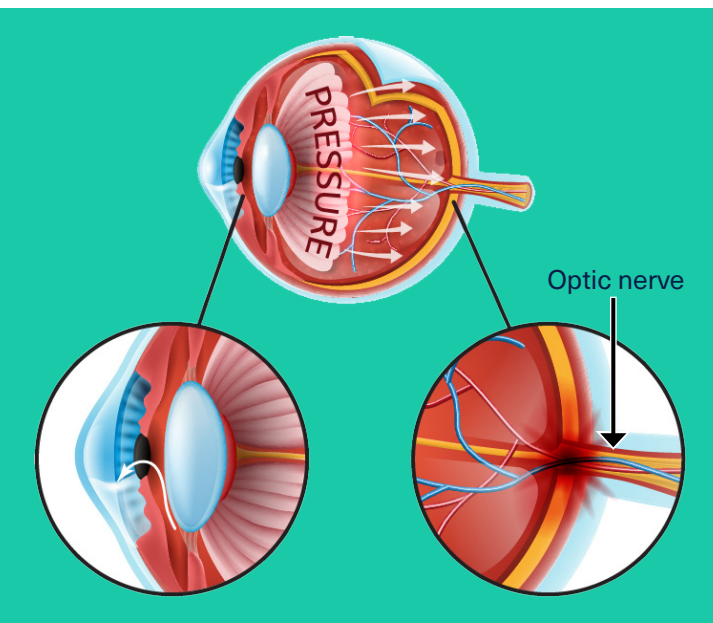
## 1.1. What was the main objective of this study?



Researchers are looking for a better way to treat open-angle glaucoma and ocular hypertension.

- **Open-angle glaucoma** is the most common type of glaucoma, an eye disease that causes the eye pressure to be too high. The increased pressure is due to a buildup of fluid in the eye, which may lead to optic nerve damage and vision loss.
- **Ocular hypertension** is an increased pressure in the eye due to a buildup of fluid which may be caused by various eye conditions. Patients with ocular hypertension do not have optic nerve damage or vision loss; however, they may be at risk of developing glaucoma.

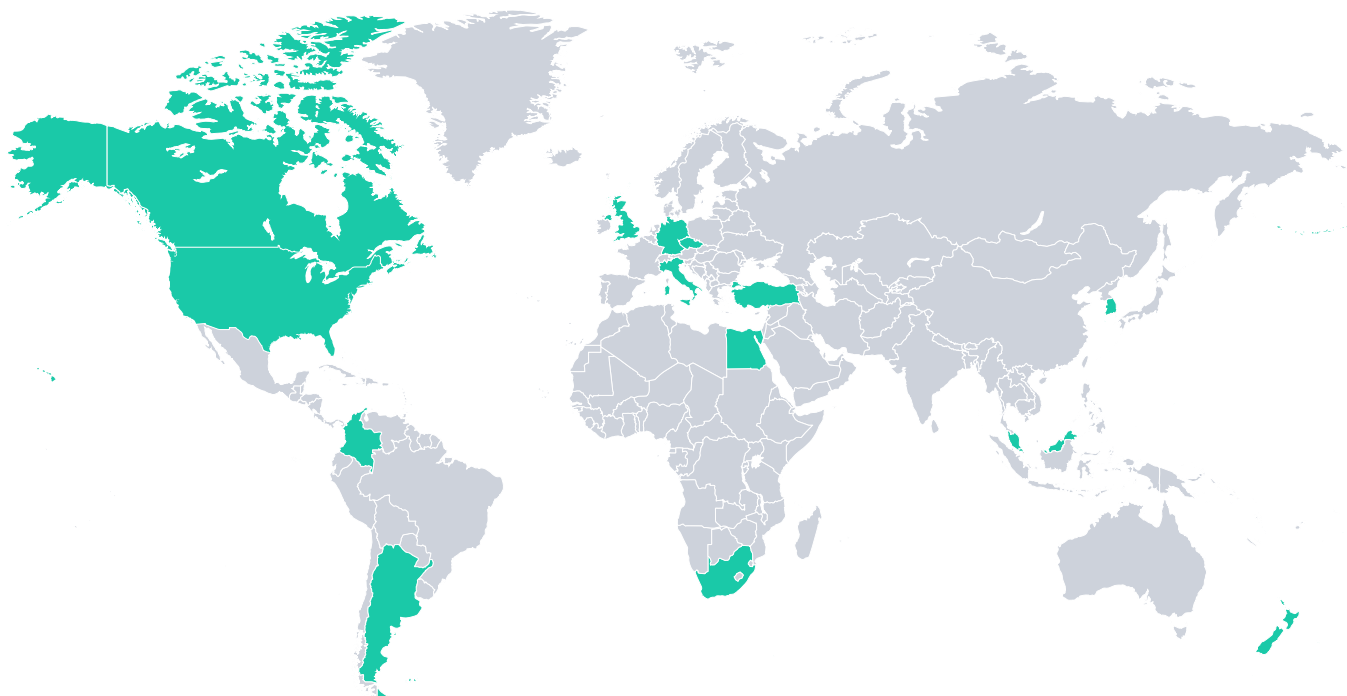
Researchers in this study used a medicine called bimatoprost SR. Bimatoprost SR works to provide long-term control of lowered eye pressure and does not require patients to take a daily medication. The main goal of the study was to learn how safe and effective two different doses of bimatoprost SR were compared to treatment with timolol, an approved drug for lowering eye pressure, to see which treatment was most effective in lowering eye pressure in patients with open-angle glaucoma or ocular hypertension. Researchers planned this study as a Phase 3, randomized 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 benefits of bimatoprost SR versus timolol in patients with open-angle glaucoma or ocular hypertension. The study doctors also looked for any side effects patients may have had after treatment with bimatoprost SR or timolol. Side effects are medical events considered by the study doctors to be at least possibly related to study drug/treatment.
- A computer program was used to randomly (by chance) put the patients into 1 of 3 treatment groups. This process is called **randomization**, which helps make the groups similar and reduces the differences between the groups.

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

This study took place from December 2014 to July 2020 in the following countries: Argentina, Canada, Colombia, Czechia, Egypt, Germany, Italy, Malaysia, New Zealand, Singapore, South Africa, South Korea, Turkey, United Kingdom, and the United States.



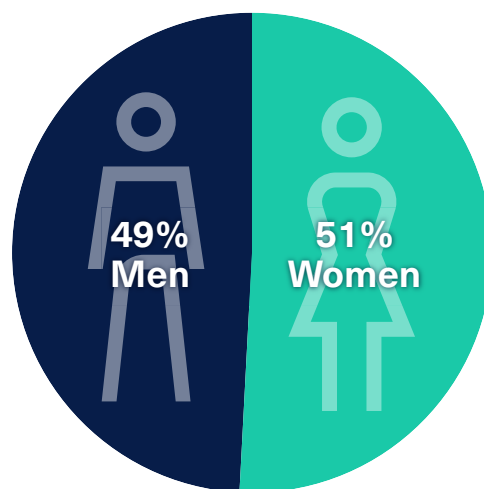
## 2. What patients were included in this study?

A total of 528 adult patients with open-angle glaucoma or ocular hypertension took part in the study. Of the 528 patients, 472 completed the study and 56 did not.

There were about the same number of men (49%) and women (51%) in the study. Patients ranged from 19 to 90 years of age. The average age of patients in the study was 62.6 years.

To participate in this study, patients had to have open-angle glaucoma or ocular hypertension in each eye that required treatment. If both eyes of a patient met study entry requirements, the eye with the higher eye pressure was assigned as the study eye. Patients were required to stop taking their usual eye pressure-lowering medication while in the study.

Patients who had previously participated in an Allergan study using bimatoprost SR could not participate in this study. Patients could also not participate if they had any other disease or abnormality of the eye which could have put the patient at risk or interfered with the completion of the study.



### 3. Which medicines were studied?

The medicine in this study is called bimatoprost SR. Bimatoprost SR is a small implant that dissolves naturally in the eye. This implant contains the drug bimatoprost. Bimatoprost SR is placed in the area between the cornea (the clear part of the eye) and the iris (the colored part of the eye). After bimatoprost SR is placed in the eye, the drug is slowly released and the implant gradually dissolves.

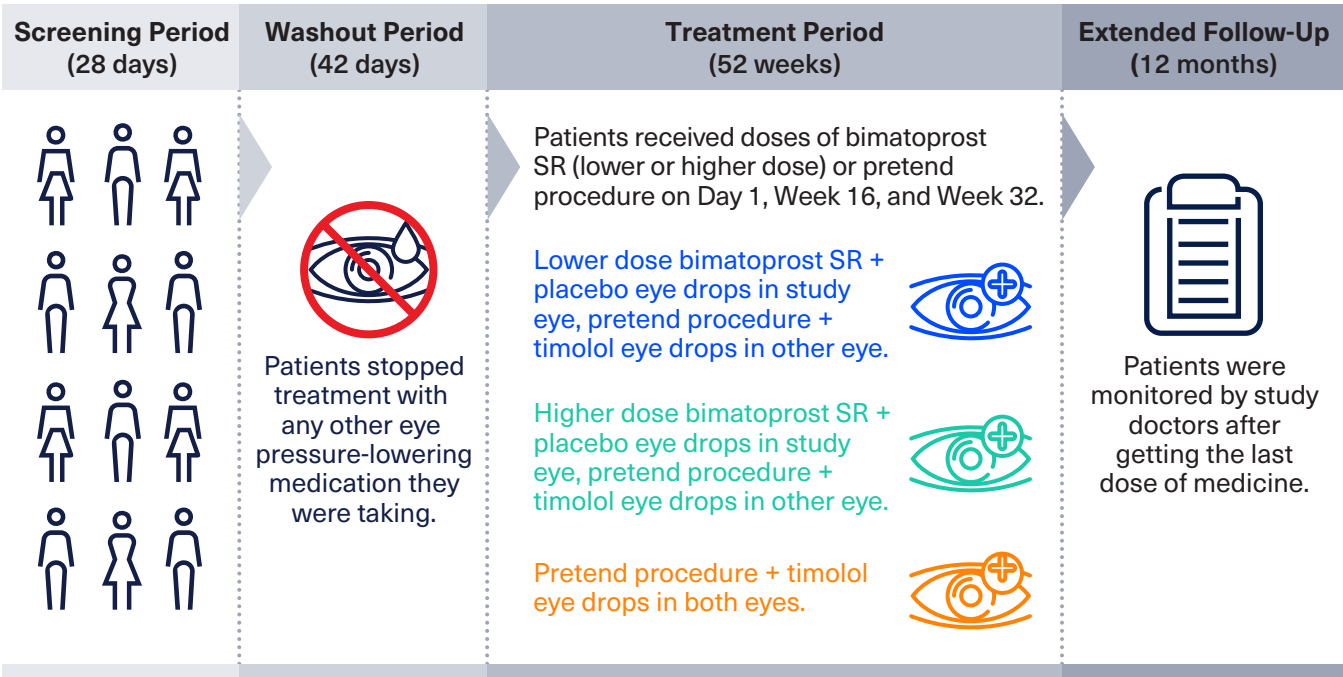
This study was split into 4 periods: the Screening Period, Washout Period, Treatment Period, and Extended Follow-Up. During the Screening Period, the study doctors selected patients who met all the requirements of the planned study. During the Washout Period, patients stopped treatment with any other eye pressure-lowering medication they were taking.

In the Treatment Period, a computer program was used to randomly (by chance) put patients into 1 of 3 groups:

1. Patients in the first group received a lower dose of bimatoprost SR plus placebo eye drops in the study eye and a pretend procedure (without an implant being administered) plus timolol eye drops in the other eye.
2. Patients in the second group received a higher dose of bimatoprost SR plus placebo eye drops in the study eye and a pretend procedure plus timolol eye drops in the other eye.
3. Patients in the third group received a pretend procedure plus timolol eye drops in each eye. This means that the patients in the third group only received timolol, and no other treatment.

Patients received doses of bimatoprost SR or a pretend procedure on Day 1, Week 16, and Week 32.

During the Extended Follow-Up, patients were monitored by study doctors after getting the last dose of study medicine. The diagram below shows how the study was organized.





## 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.

About 6.3% of patients (11 patients) in the bimatoprost SR higher dose group, 2.9% of patients (5 patients) in the bimatoprost SR lower dose group, and no patients in the timolol group had serious side effects during the study.

About 9.1% of patients (16 patients) in the bimatoprost SR higher dose group, 2.3% of patients (4 patients) in the bimatoprost SR lower dose group, and 1.2% of patients (2 patients) in the timolol group stopped taking the study drug because of side effects during the study.

No patient died during the study due to side effects.

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.

Overall Study			
	Bimatoprost SR Higher Dose Group (176 Patients)	Bimatoprost SR Lower Dose Group (175 Patients)	Timolol Group (173 Patients)
Number of patients with serious side effects	11 (6.3% of patients)	5 (2.9% of patients)	0 (0.0% of patients)
Serious Side Effects			
• Cell loss of the cornea (corneal endothelial cell loss)	8 (4.5%)	3 (1.7%)	0 (0.0%)
• Swelling of the cornea (corneal edema)	2 (1.1%)	1 (0.6%)	0 (0.0%)
• Breakdown of the cornea (corneal decompensation)	0 (0.0%)	1 (0.6%)	0 (0.0%)
• Fluid build-up in the macula (macular edema)	1 (0.6%)	0 (0.0%)	0 (0.0%)
Number of patients who stopped taking study drug because of side effects	16 (9.1%)	4 (2.3%)	2 (1.2%)
Reasons for stopping	Breakdown of the cornea, corneal disorder, cell loss of the cornea, corneal touch (when the eye's lens touches the cornea), implantation of study drug delivery device, increased eye pressure, inflammation of the iris (colored part of the eye) and the ciliary body (circular structure around the eye) (iridocyclitis), inflammation of the iris (iritis), light intolerance (photophobia), sensation of foreign material in the eyes, swelling of the cornea	Breakdown of the cornea, chronic obstructive pulmonary disorder, inappropriate administration of product in the eye, swelling of the cornea	Allergic reaction to a drug (drug hypersensitivity), pink eye (conjunctivitis)

About 61.9% of patients (109 patients) in the bimatoprost SR higher dose group, 48.0% of patients (84 patients) in the bimatoprost SR lower dose group, and 20.8% of patients (36 patients) in the timolol group had side effects during the study. The table below shows information about the common side effects (in at least 11 or more patients in any treatment group) in this study. The most common side effects were increased blood flow to the eye and cell loss of the cornea.

Overall Study			
	Bimatoprost SR Higher Dose Group (176 Patients)	Bimatoprost SR Lower Dose Group (175 Patients)	Timolol Group (173 Patients)
Number of patients with at least one side effect	109 (61.9% of patients)	84 (48.0% of patients)	36 (20.8% of patients)
Common Side Effects			
Increased blood flow to the eye (conjunctival hyperemia)	48 (27.3%)	37 (21.1%)	10 (5.8%)
Cell loss of the cornea	40 (22.7%)	11 (6.3%)	0 (0.0%)
Eye pain	18 (10.2%)	10 (5.7%)	6 (3.5%)
Swelling of the cornea	17 (9.7%)	4 (2.3%)	0 (0.0%)
Broken blood vessels in the eye (conjunctival hemorrhage)	12 (6.8%)	12 (6.9%)	11 (6.4%)
Sensation of foreign material in the eyes	12 (6.8%)	10 (5.7%)	2 (1.2%)
Light intolerance	11 (6.3%)	8 (4.6%)	0 (0.0%)

Across the whole study, patients in the bimatoprost SR higher dose group experienced more side effects compared to patients who received bimatoprost SR lower dose or timolol.

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

The study was completed as planned and demonstrated that bimatoprost SR can effectively reduce the eye pressure in patients with open-angle glaucoma or ocular hypertension. The study results showed that patients who received bimatoprost SR (lower or higher dose) saw at least as much improvement in reduced eye pressure when compared to patients who received timolol from the start of the study to Week 2, Week 6, and Week 12 of treatment.

Patients in the bimatoprost SR higher dose group experienced more side effects compared to patients who received bimatoprost SR lower dose or timolol.

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

The study has helped researchers to learn more about the safety and effectiveness of bimatoprost SR for the treatment of patients with open-angle glaucoma and ocular hypertension. It showed that both doses (higher and lower) of bimatoprost SR showed similar effectiveness to timolol in lowering eye pressure at Week 2, Week 6, and Week 12 of treatment. Bimatoprost SR can provide sustained, long-term treatment for patients with open-angle glaucoma and ocular hypertension, and does not require patients to take a daily medication.

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 bimatoprost SR.

## 7. Are there any plans for future studies?

Multiple bimatoprost SR studies are ongoing.

## 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	The Efficacy and Safety of Bimatoprost SR in Patients With Open-angle Glaucoma or Ocular Hypertension
Protocol Number	192024-092
Clinicaltrials.gov	NCT02250651 <a href="https://clinicaltrials.gov/ct2/show/NCT02250651?term=NCT02250651&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT02250651?term=NCT02250651&amp;draw=2&amp;rank=1</a>
EudraCT	2014-003186-24 <a href="https://www.clinicaltrialsregister.eu/ctr-search/search?query=2014-003186-24">https://www.clinicaltrialsregister.eu/ctr-search/search?query=2014-003186-24</a>
Study Sponsor	AbbVie, Inc. Phone: +1 800-633-9110 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!

