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Summary of Clinical Trial Results

For Laypersons

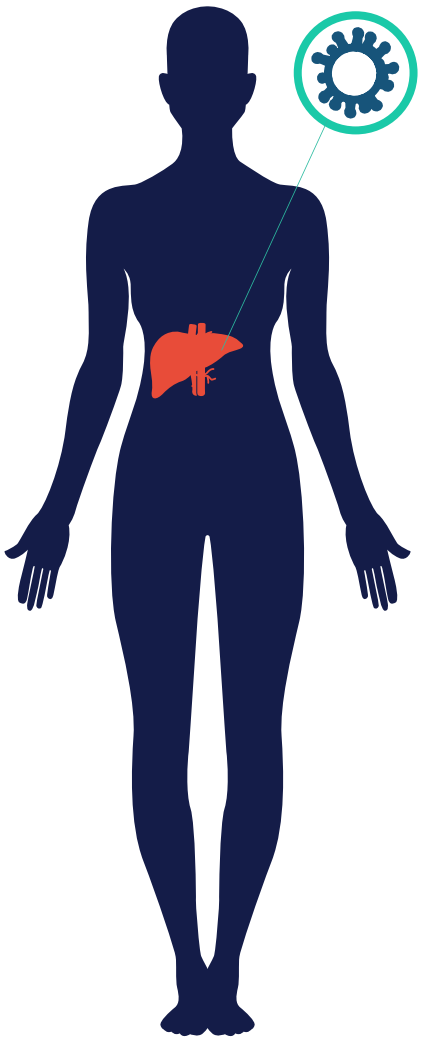
A study to learn how effective and safe a medicine containing glecaprevir and pibrentasvir works to treat Asian adult patients with long-lasting hepatitis C genotype 1 to 6 infection without liver cirrhosis (scarring of the liver)

Overall Summary

- Hepatitis C infection is a global health problem caused by a virus (a small agent that infects living organisms), which may cause disease and liver damage.
- In this study, study doctors tested a medicine made up of glecaprevir and pibrentasvir in patients who had long-lasting hepatitis C infection with genotypes 1, 2, 3, 4, 5, or 6.
- The study took place from October 2017 to February 2019 in 3 countries.
- A total of 545 adult patients took part in this study and 535 completed the study.
- Patients took 3 tablets of 100 milligrams (mg) glecaprevir and 40 mg pibrentasvir or placebo (no real medicine).
- The results of the study may be used by researchers to further develop this medicine. If you participated in this study and wish to see your results, contact the doctor or staff at your study site.
- A total of 97.2% of patients with hepatitis C genotype 1-6 virus did not have detectable hepatitis C virus 12 weeks after they finished taking glecaprevir and pibrentasvir during the double-blind period of the study. About 99.4% of patients with hepatitis C genotype 1 virus and 97.8% of patients with hepatitis C genotype 2 virus did not have detectable hepatitis C virus 12 weeks after they finished taking glecaprevir/pibrentasvir.
  - Two patients had the virus come back while they were taking glecaprevir/pibrentasvir.
  - Six patients had the virus come back within 12 weeks after they finished taking glecaprevir/pibrentasvir.
- Most of the side effects were mild. The percentages of patients with side effects were similar between patients who received glecaprevir/pibrentasvir and patients who received placebo. No patients had serious side effects related to the study drug, no patients stopped taking the study drug due to side effects related to the study drug, and no patient died during the study.

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 liver disease called hepatitis C, which is caused by the hepatitis C virus. The doctors in this study selected Asian patients who had hepatitis C virus genotypes (different types) 1 to 6 without liver cirrhosis (scarring of the liver). Patients may or may not have received treatment for hepatitis C prior to this study.

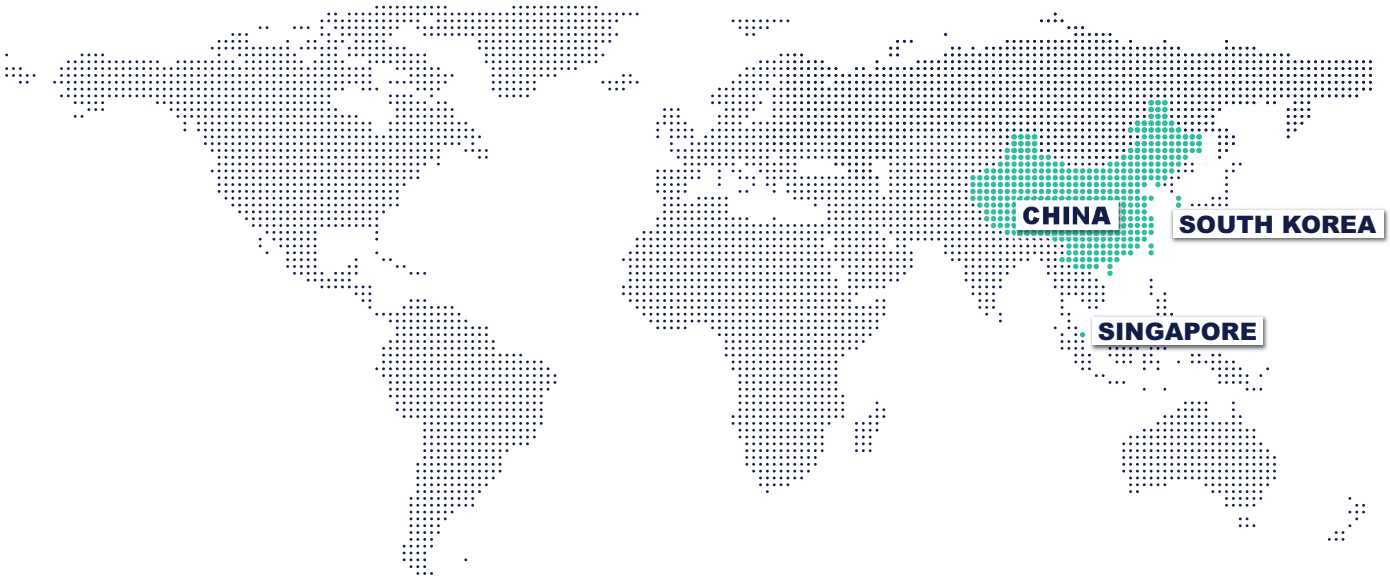
In this study, the researchers wanted to find out how well glecaprevir and pibrentasvir would benefit patients when given together. Glecaprevir and pibrentasvir are two drugs that may stop the hepatitis C virus from multiplying. When taken together, these drugs may stop any of the six major genotypes (genotypes 1, 2, 3, 4, 5 and 6) of the hepatitis C virus. Researchers used a placebo to compare the results for patients who took the combined glecaprevir and pibrentasvir medicine with the results for patients who took no medicine at all (placebo). A placebo looks like the treatment medicine but has no active drug in it.

Researchers planned this study as a Phase 3, randomized study with double-blind and open-label periods. Phase 3 studies test potential new treatments in a large number of patients with a condition or disease. This study had a “double-blind” period, which means that neither the patients nor the study doctors knew who was given which study drug (combined glecaprevir and pibrentasvir or placebo). This ensures that no study results were influenced. This study also had an “open-label” period, which means that both the patients and the study doctors knew which treatment was given. Patients in this study were “randomized” into different study arms. Randomization is the process where patients are randomly (by chance) placed into different groups.

The main aim of the study was to find out if the hepatitis C virus was no longer found in the bloodstream of patients 12 weeks after taking the combined medicine. Researchers also checked if there were any unwanted side effects. This summary only includes the results of this study, which may be different from the results of other studies.

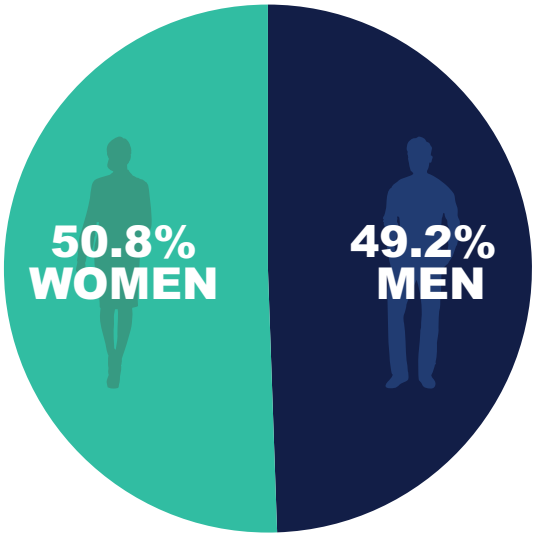
1.2 When and where was the study done?

This study took place from October 2017 to February 2019 in the following locations:



2. What patients were included in this study?

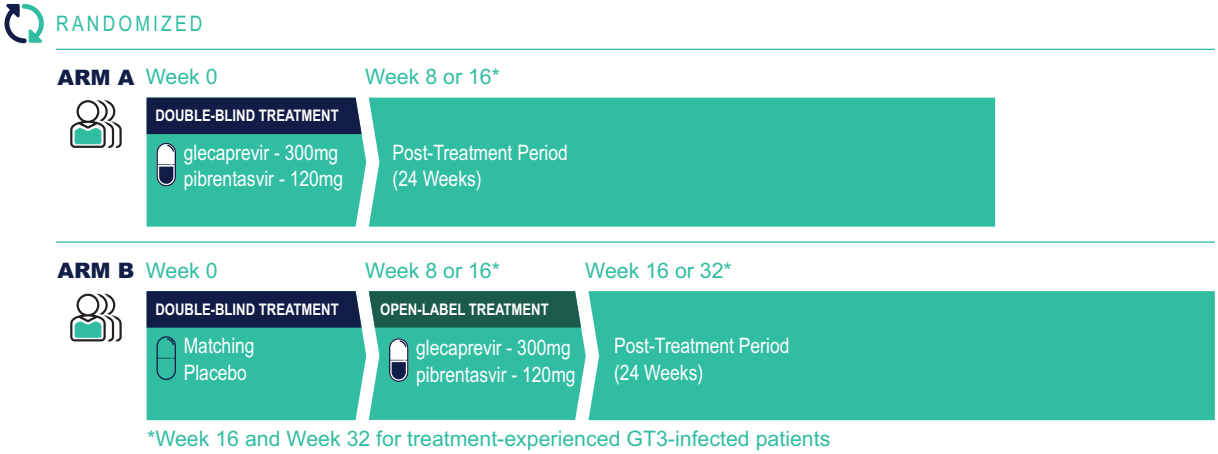
A total of 545 Asian adult patients with long-lasting hepatitis C took part in the study. Of these, 535 patients completed the study and 10 patients did not. Five patients left the study by personal choice, 1 patient was lost to follow-up (patient did not return to continue treatment or testing), and 4 patients left the study for other reasons. In the double-blind period, 362 patients received glecaprevir/pibrentasvir and 183 patients received placebo; 182 of the patients who received placebo continued on to the open-label period to receive glecaprevir/pibrentasvir.



About the same number of men (49.2%) and women (50.8%) participated in the study. Study doctors selected only adults in this study. Patients ranged from 19 to 85 years of age. No patient had cirrhosis or was infected with human immunodeficiency virus (HIV). A majority of the patients (80.0%) were receiving treatment for hepatitis C for the first time in this study.

3. Which medicines were studied?

The medicine in this study was the combination of two study drugs called glecaprevir and pibrentasvir. The diagram below shows how the study was organized.



The study was divided into 3 parts: the double-blind period, the open-label period, and the post-treatment period. At the beginning of the study, the study doctors selected patients who met all the requirements of the planned study. In the double-blind period, patients were randomly assigned to Arm A or Arm B based on the region where they lived, their hepatitis C virus genotype, and their HIV status. Patients in Arm A were given the combined glecaprevir and pibrentasvir medicine for 8 weeks or 16 weeks. Patients in Arm B were given placebo for 8 weeks or 16 weeks, followed by an open-label period, where they received the combined glecaprevir and pibrentasvir medicine for 8 weeks or 16 weeks. Treatment duration during the double-blind period and open-label period depended on hepatitis C genotype and past hepatitis C treatment experience.

Patients took 3 tablets of 100 milligrams (mg) glecaprevir and 40 mg pibrentasvir with food once a day or 3 placebo tablets matching the study drug with food once a day.

During the post-treatment period, patients who had received glecaprevir and pibrentasvir were again contacted by study doctors and tested for 24 weeks after getting the last dose of medicine. Blood samples were taken to detect any signs of hepatitis C virus in the bloodstream and to see if the hepatitis C virus changed to be resistant to the study drug.

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 patient in the hospital, keeps a patient in the hospital for a long time, or causes a disability that lasts a long time.

Related side effects are side effects that were at least possibly related to the study drug.

4.1. What were the serious side effects?

In the double-blind period, about 0.8% of patients (3 patients) in Arm A and 2.2% of patients (4 patients) in Arm B had serious side effects; of these, none were considered possibly related to the study drug. In the open-label period, about 2.7% of patients (5 patients) had serious side effects; of these, none were considered possibly related to the study drug.

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

4.2. What were the most common side effects?

In the double-blind period, about 48.6% of patients (176 patients) in Arm A and 51.9% of patients (95 patients) in Arm B had side effects. The total number of patients that had side effects considered possibly related to the study drug was 9.9% of patients (36 patients) in Arm A and 7.7% of patients (14 patients) in Arm B.

In the open-label period, about 47.8% of patients (87 patients) had side effects. The total number of patients that had side effects considered possibly related to the study drug was 7.7% of patients (14 patients).

The table below shows information about the most common related side effects (in at least 3 or more patients) in any of the groups in this study. The most common related side effect was fatigue (tiredness).

	Double-Blind Period		Open-label Period
	Arm A Glecaprevir/ Pibrentasvir (n=362 patients)	Arm B Placebo (n=183 patients)	Glecaprevir/ Pibrentasvir (n=182 patients)
Number of patients with at least one related side effect	36 (9.9% of patients)	14 (7.7% of patients)	14 (7.7% of patients)
Most common side effects in 3 or more patients			
Fatigue (tiredness)	5 (1.4% of patients)	5 (2.7% of patients)	1 (0.5% of patients)
Dyspepsia (indigestion)	3 (0.8% of patients)	1 (0.5% of patients)	0 (0.0% of patients)
Nausea	3 (0.8% of patients)	2 (1.1% of patients)	2 (1.1% of patients)
Blood creatine phosphokinase increased (blood protein level increased)	3 (0.8% of patients)	0 (0% of patients)	0 (0% of patients)
Dizziness	3 (0.8% of patients)	2 (1.1% of patients)	2 (1.1% of patients)
Blood bilirubin increased (higher levels of a blood component called bilirubin)	0 (0% of patients)	0 (0% of patients)	3 (1.6% of patients)
Pruritus (itchiness)	0 (0% of patients)	0 (0% of patients)	3 (1.6% of patients)

5. What were the overall results of the study?

The study was completed as planned. A total of 97.2% of patients with hepatitis C genotypes 1-6 virus did not have detectable hepatitis C virus 12 weeks after they finished taking glecaprevir/pibrentasvir during the double-blind period of the study. About 99.4% of patients with hepatitis C genotype 1 virus and 97.8% of patients with hepatitis C genotype 2 virus did not have detectable hepatitis C virus 12 weeks after they finished taking glecaprevir/pibrentasvir. Two patients had the virus come back while they were taking glecaprevir/pibrentasvir in the double-blind period. Six patients had the virus come back within 12 weeks after they finished taking glecaprevir/pibrentasvir in the double-blind period. Most of the side effects were mild. The percentages of patients with side effects were similar between patients who received glecaprevir/pibrentasvir and patients who received placebo. No patients had serious side effects related to the study drug, no patients stopped taking the study drug due to side effects related to the study drug, and no patient died during the study.

6. How has the study helped patients and researchers?

The results of this study showed that the benefits were greater than the risks in the treatment of all hepatitis C virus genotypes (1-6) with the glecaprevir/pibrentasvir combination medicine. Findings from this study may be used in other studies to learn whether patients are helped by the study drug.

This summary only shows the results of this study, which may be different from the results of other studies. 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 is a possibility for future studies that include the medicine that was used in this study.

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 Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of ABT-493/ABT-530 in Treatment-Naïve and Treatment-Experienced, Non-Cirrhotic Asian Adults With Chronic Hepatitis C Virus Genotype (GT) 1 to GT6 Infection With or Without Human Immunodeficiency Virus Co-Infection
Protocol Number	M15-592
ClinicalTrials.gov	NCT03222583 https://clinicaltrials.gov/ct2/show/NCT03222583?term=NCT03222583&rank=1
Study Sponsor	Global Medical Services, AbbVie Phone: +1 800-633-9110 Email: abbvieclinicaltrials@abbvie.com

01 Dec 2019. This document includes known facts as of the time the document was finalized.

AbbVie wants to thank all the participants and their families for their time and effort that went into making this study possible.

Clinical study participants help advance science!

THANK YOU!