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Summary of Clinical Trial Results

For Laypersons

A study to learn how well and safe a medicine containing glecaprevir and pibrentasvir works to treat adult patients with long-lasting hepatitis-C infection and kidney damage

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.
- Infection with the hepatitis C virus is common in patients with kidney damage undergoing dialysis, a procedure to remove body waste and excess water to balance the body when the kidney fails.
- Study doctors tested a medicine made up of glecaprevir and pibrentasvir in patients who had both long-lasting hepatitis C infection and kidney disease.
- Some of the patients had cirrhosis (severe liver scarring) and some did not.
- The study took place in 10 countries from March 2017 to June 2018.
- Total 101 adults took part in the study and 98 of them completed the study.
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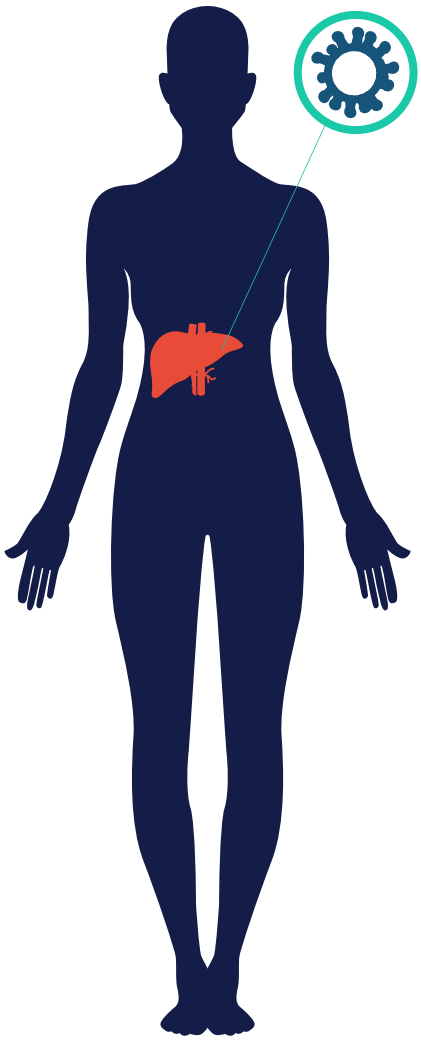
- The study doctors put the patients into three groups. Each group was given the same dose of medicine for a different period of time.
- None of the patients had their hepatitis C come back again while they were taking the medicine.
- None of the patients had any serious side effects caused by the study drug.
- The results of this study may be used by researchers to further develop this medicine.

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 a virus. Long-lasting hepatitis C infection tends to develop a condition called cirrhosis. Cirrhosis is scarring of the liver, which damages the liver and makes it difficult to function normally. Long-lasting liver infection with hepatitis C virus is common among patients in the last stage of long-term kidney disease undergoing dialysis. So, the doctors in this study selected hepatitis C infected patients suffering from kidney disease with or without cirrhosis to test new medicines.

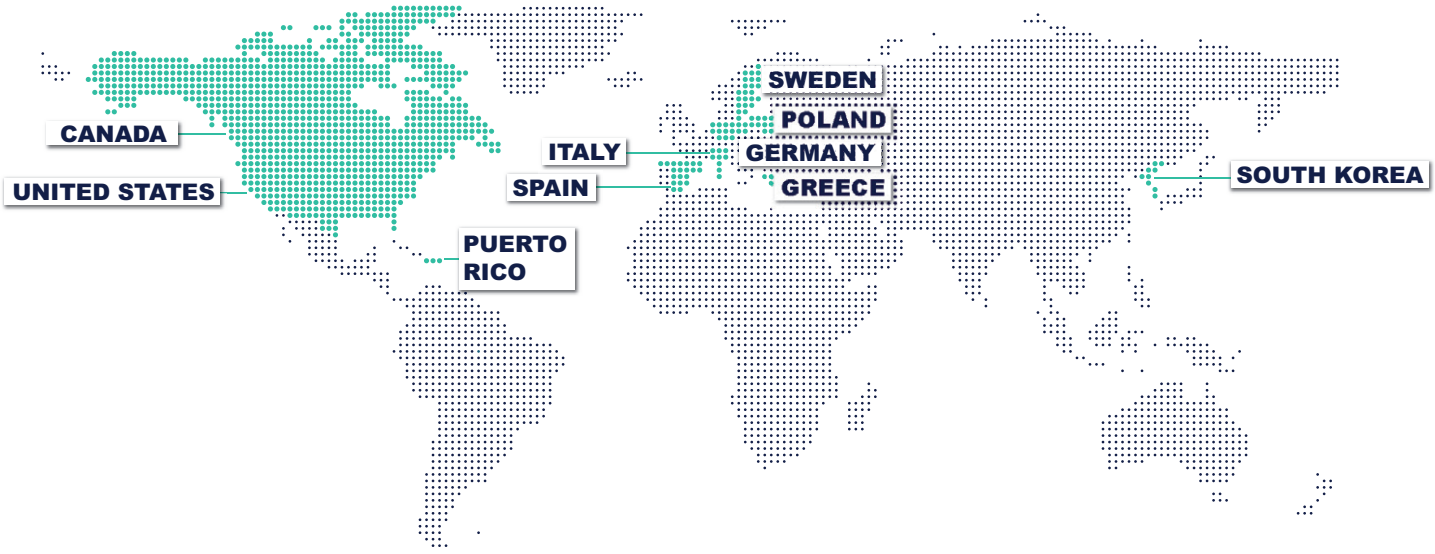
In this study, the researchers wanted to find out how well glecaprevir and pibrentasvir would benefit patients when given together. Glecaprevir and pibrentasvir are two drugs that may stop the virus from multiplying. Both of the drugs may stop all six major genotypes (different types) of the hepatitis C virus.

Researchers planned this study as a Phase 3 open-label study. Phase 3 studies test potential new treatments in a large number of patients with a condition or disease. In this Phase 3b study, the study doctors looked at the benefits of the combined study drugs over 8, 12, or 16 weeks in patients with hepatitis C infection. The study doctors also looked for any side effects the patients may have had during and after treatment with the study drug. The study was open-label, which means the researchers and the patients knew what they were taking.

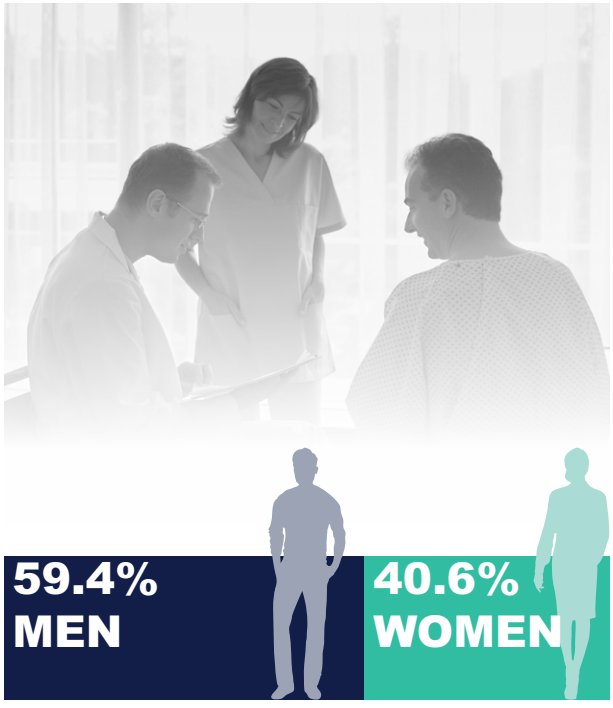
The main aim of the study was to confirm if the hepatitis C virus was no longer in the bloodstream of patients 12 weeks after taking the combined medicine. Researchers also checked if there were any unwanted side effects. This summary only includes the results of this study, which may be different from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

1.2 When and where was the study done?

This study took place from March 2017 to June 2018 in the following locations:



2. What patients were included in this study?



A total of 101 adult patients with long-lasting hepatitis C took part in the study. All patients had long-term kidney disease, with or without liver cirrhosis. Among the 101 patients, 98 completed taking their medicine and 3 did not: 1 patient failed to follow the instructions to take medicine, and the other 2 stopped taking the study drug due to side effects.

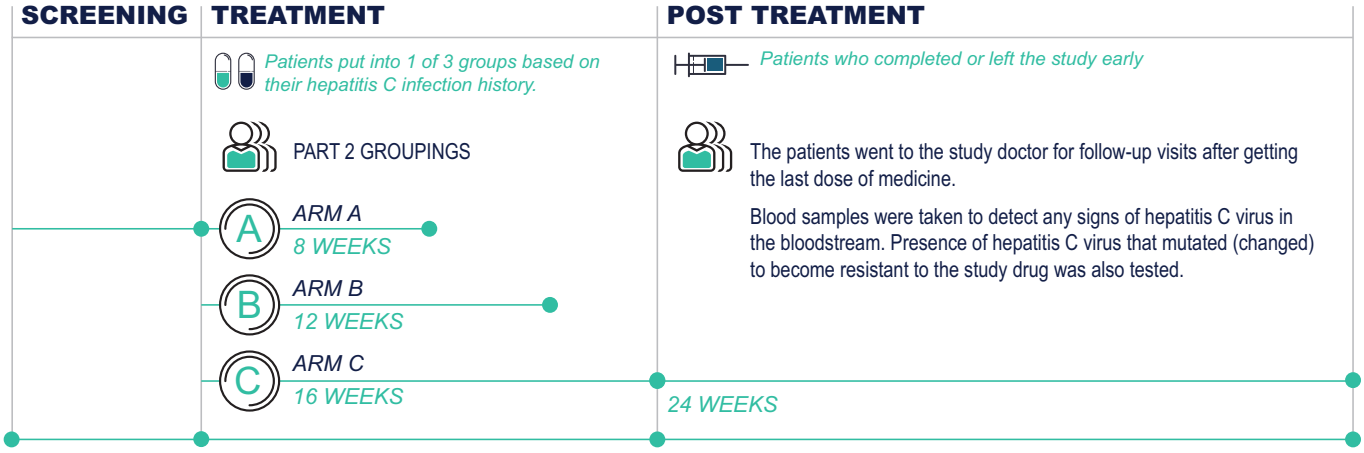
There were more men (59.4%) than women (40.6%) in the study. Study doctors selected only adults in this study. Patients ranged from 32 to 87 years of age. Of the total patients, most (80.2%) were getting hepatitis C medicines for the first time, most (76.2%) needed dialysis, and most (87.1%) did not have liver cirrhosis

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.

Group	Drug
Arm A	Genotype 1, 2, 4-6 NC, TN & TE, and genotype 3 NC, TN
Arm B	Genotype 1, 2, 4-6 C, TN & TE, and genotype 3 C, TN
Arm C	Genotype 3 NC & C, TE

TN = Treatment-naive | TE = Treatment experienced | NC = Non-cirrhotic | C = Cirrhotic



At the beginning of the study, the study doctors selected patients who met all the requirements of the planned study in the screening period of 42 days. Patients were divided into 3 groups: Patients were given medicine for 8 weeks in the first group (Arm A), 12 weeks in the second group (Arm B), and 16 weeks in the third group (Arm C). All patients got the same dose of medicine. Patients took 3 tablets of 100 milligrams (mg) glecaprevir and 40 mg pibrentasvir with food once daily.

During the post-treatment period, patients who had received study drug 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 hepatis C virus mutated (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 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 at least possibly related to study drug.

About 11.9% of patients (12 patients) had serious side effects; of these, 0% of patients had related serious side effects during the study.

About 2.0% of patients (2 patients) stopped taking the study drug because of side effects; of these, 1.0% of patients (1 patient) stopped taking the study drug because of a side effect (pruritus [itchy skin]) that was related to study drug.

No patients died during the study.

The table below shows information about the related serious side effects patients had in different parts of the study, as well as related side effects patients had that led to the patient stopping the study drug, and related side effects leading to death.

	OVERALL (n=101)
Number of patients with related serious side effects	0 (0% of patients)
Number of patients who stopped taking study drug because of related side effects	1 (1.0% of patients)
Reason(s) for stopping	Pruritus (itchy skin)
Number of patients with related side effects leading to death	0 (0% of patients)

About 24.8% of patients (25 patients) had a related side effect during the study. The table below shows information about related side effects in this study. The most common related side effects were pruritus (itchy skin) and pruritus generalized (itchy skin over the body).

	OVERALL (n=101)
Number of patients with at least one related side effect	25 (24.8% of patients)
Side Effects	
Pruritus (itchy skin)	15 (14.9% of patients)
Pruritus generalized (itchy skin over the body)	6 (5.9% of patients)
Fatigue (tiredness)	2 (2.0% of patients)
Myalgia (muscle pain)	2 (2.0% of patients)
Upper abdominal pain	1 (1.0% of patients)
Asthenia (weakness)	1 (1.0% of patients)
Dry skin	1 (1.0% of patients)
Flatulence (passing gas)	1 (1.0% of patients)
Headache	1 (1.0% of patients)
Herpes virus infection	1 (1.0% of patients)
Influenza (flu)-like illness	1 (1.0% of patients)
Migraine	1 (1.0% of patients)

5. What were the overall results of the study?

The study was completed as planned. Most of the patients (98 out of 101 [97%]) did not have hepatitis C 12 weeks after they stopped taking the medicine. No patient was detected with a virus while they were taking the medicine. No patient had a relapse (the virus came back) in the 12 weeks after they finished taking the medicine. Most of the side effects were mild. None of the patients faced any serious side effects.

6. How has the study helped patients and researchers?

The results of this study showed that the benefits were greater than the risks in all 1-6 genotypes of the hepatitis C virus. 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 from 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 are currently no plans for future studies in this patient population 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 Multicenter, Open-Label Study to Evaluate the Efficacy and Safety of Glecaprevir/Pibrentasvir in Renally-Impaired Adults with Chronic Hepatitis C Virus Genotype 1 – 6 Infection (EXPEDITION-5)
Protocol Number	M16-127
ClinicalTrials.gov	NCT03069365 https://clinicaltrials.gov/ct2/show/NCT03069365?term=M16-127&rank=1
EudraCT	2016-004182-60 https://www.clinicaltrialsregister.eu/ctr-search/trial/2016-004182-60/results
Study Sponsor	Global Medical Services, AbbVie Phone: 800-633-9110 Email: abbvieclinicaltrials@abbvie.com

31 May 2019. This document includes known facts as of the time the document was finalized.

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!

THANK YOU!