

Clinical Trial Summary

Efficacy and Safety of Atorvastatin + Perindopril Fixed-Dose Combination S05167 in Adult Patients With Arterial Hypertension and Dyslipidemia

Full scientific title: Efficacy and safety of Atorvastatin/Perindopril Fixed-Dose Combination S05167 in adult patients with arterial hypertension and dyslipidaemia, 8 weeks, phase 3, randomised, double-blind, active-control, multinational, multi-centre, parallel study

We thank all the participants who took part in the study. Clinical study participants are very important for making progress in science, for the benefit of patients.

This document is a summary of the study. It is written for a general audience.

Researchers need many studies to decide which medicines work the best and are the safest for patients. For medical science to progress, many studies involving patients are running all around the world. This summary only shows the results from this one study. Other studies, evaluating the same drug, may find different results. You should not change your current treatment based on the results of this single study. If you have any questions about this study, please talk to your doctor.

Therapeutic area:
Cardiology

Disease:
Arterial
hypertension and
dyslipidaemia

Study phase:
Phase 3

Final version
19/12/2023

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1 Why was this study done?

This study was done to test the combination of 2 drugs - atorvastatin and perindopril in a single capsule (called S05167) in patients with high blood pressure and dyslipidaemia.

High blood pressure is a common health condition that may cause or increase the risk of health problems. Doctors make the diagnosis by measuring blood pressure. When blood pressure is measured, two values are recorded. The higher value is called systolic blood pressure (SBP). The lower value is called diastolic blood pressure (DBP). Blood pressure is written as SBP/DBP. For example, 120/80 mmHg (millimetres of mercury).

Dyslipidaemia is a condition in some of the lipids (fats) in the blood are too high. Doctors make the diagnosis by measuring lipids such as cholesterol in the blood.

Patients need different drugs to treat their high blood pressure and high cholesterol. When this happens, patients may forget to take one of them or may dislike taking several pills. For these reasons, the researchers have developed the study drug which contains both treatments in one capsule.

The study drug is a capsule containing 2 drugs: atorvastatin and perindopril. Both these drugs are already approved and marketed.

Perindopril lowers the blood pressure by widening the blood vessels. This makes it easier for the heart to pump the blood through them.

Atorvastatin lowers the cholesterol in the blood by blocking a step in the production of cholesterol in the body.

The main goals of this study were to test:

- If S05167 works better than atorvastatin alone in lowering high systolic blood pressure (SBP).
- If S05167 works better than perindopril alone in lowering cholesterol levels.

2 When and where did this study take place?

When did the study take place?

- This study started in September 2021.
- It ended in April 2022.

Where did the study take place?

The study took place in 3 countries (Georgia, Russia, and Ukraine). A total of 147 patients were included in the study.

3 Who participated in the study?

Which participants were included in the study?

To take part, participants had to:

- Be 18 to 79 years old.
- Have high blood pressure (either of the below):
 - For participants who are already on medication for high blood pressure:
 - The SBP was between 140 and 160 mmHg.
 - The DBP was between 90 and 100 mmHg.
 - For participants who have not taken any medication for high blood pressure:
 - The SBP was between 150 and 160 mmHg.
 - The DBP was between 90 and 100 mmHg.
- Have high cholesterol levels: LDL (low-density lipoprotein) cholesterol (called “bad” cholesterol) between 110 milligrams (mg) per deciliter (mg/dL) and 190 mg/dL.

How many participants took part in the study?

A total of 147 participants took part in the study: 85 women and 62 men.

How old were the participants?

The average age of the participants was 54 years. The youngest participant was 26 years old and the oldest was 79 years old.

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4 Which treatments did the participants receive?

Participants received one of the following treatments orally once daily for 8 weeks:

- S05167: one single capsule of a combination of atorvastatin 40 mg and perindopril 10 mg.
- Atorvastatin capsule at a dose of 40 mg.
- Perindopril capsule at a dose of 10 mg.

5 How was the study carried out?

The study is called a “randomised” study. This means that the participants were put by chance into one of the 3 groups of treatment (mentioned above).

Participants had equal chances to be assigned to the S05167 group or the atorvastatin group. The chances of being assigned to the perindopril group were half.

Among the 147 participants included in the study:

- 59 participants took S05167.
- 59 participants took atorvastatin.
- 29 participants took perindopril.

The participants took the treatment for around 8 weeks.

The study is called a “double-blind” study. This means that neither the participants nor the research doctors knew which treatment was taken. This was to avoid any influence on the results.

The participants visited the doctors regularly. During the visits, the doctors collected information about the participants’ health.

6 What were the side effects?

Side effects are unwanted medical events that the doctors think may be caused by the treatments in the study.

In this summary, we describe unwanted medical events thought to be caused by S05167, atorvastatin, and perindopril. The results may be presented differently in other documents related to the study.

- One participant (out of 59 participants) in the atorvastatin group had side effects.
- No participants had serious* side effects.
- No participants stopped the treatment because of side effects.

**See definition of serious side effects below*

What were the types of side effects?

One participant in the atorvastatin group had experienced an increase in liver enzymes called ALT and AST.

What were the serious side effects?

A side effect is considered serious when:

- the participant needs to be hospitalised,
- it causes lasting damage or death,
- the participant’s life is in danger or,
- it is medically important in the doctor’s opinion.

In this study, no participants had serious side effects (serious unwanted medical events thought to be caused by the treatments in the study).

In the study, no participants died.

7 What were the study results?

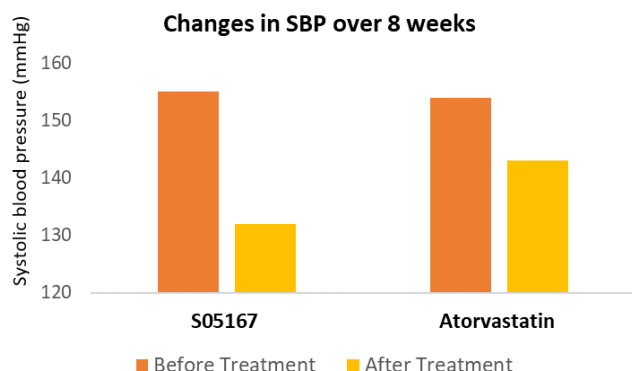
This study was stopped earlier than planned. Due to strategic reasons, the sponsor decided to stop the development of the study drug. This decision was not due to the safety of the study drug.

This document presents only the results for the main goal of the study. Other results are available in other documents listed in section 10.

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The study found that after 8 weeks of treatment, participants who took S05167 showed a higher decrease in SBP than participants who took atorvastatin alone.



The study also found that participants who took S05167 showed higher decrease in cholesterol levels than participants who took perindopril alone. However, the difference between the cholesterol values obtained for S05167 and perindopril alone was not large enough and the researchers cannot conclude definitely whether there is a true (significant) difference.

8 How has this study helped research?

This study helped researchers to gather more information on S05167 in participants with high blood pressure and high cholesterol levels.

This summary shows only the main results from this one study. Other studies, evaluating the same drug, may find different results.

9 Are there plans for further studies?

The sponsor has decided to stop testing S05167. No other studies with S05167 are planned so far.

10 Further information

What are the identification numbers of the study?

- Protocol code: CL3-05167-005
- US NCT number: NCT04591808

Who did the study?

The company that organised and funded the research, called the “sponsor”, is the Institut de Recherches Internationales Servier based in Suresnes, France.

How can you contact the sponsor?

Contact us on the Servier website

<https://servier.com/en/>

Where can you learn more about this study?

You can find more information about this study on these websites:

- <https://clinicaltrials.servier.com/find-clinical-trials>
- <http://www.clinicaltrials.gov/>

In this document we translated medical terms into lay terms. You can find the corresponding medical terms in the Servier glossary at

<https://clinicaltrials.servier.com/glossary/>

You can find general information about clinical trials on <https://clinicaltrials.servier.com/>