



# Clinical Trial Summary

## A study of a combined treatment in patients with high blood pressure.

**Full scientific title:** *Evaluation of the clinical efficacy and safety of Amlodipine 5mg/ Bisoprolol fumarate 5mg /Perindopril arginine 5mg fixed-dose combination in capsule and free monotherapy at the same dose in patients with uncontrolled essential hypertension. A multicentre, randomized, open-label, 12-weeks 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:  
Cardiovascular

Disease:  
Uncontrolled  
essential hypertension

Study phase:  
Phase 3

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Final version

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## A study of a combined treatment in patients with high blood pressure

### 1 Why was this study done?

This study was done to test the study drug called amlodipine/bisoprolol/perindopril (a single capsule) in patients with high blood pressure, despite undergoing treatment for this condition.

High blood pressure is a common condition that may cause health problems, such as heart diseases. 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 systolic pressure/diastolic pressure. For example, 120/80 mmHg (millimeters of mercury).

Some patients can have their blood pressure well controlled with a single drug treatment. Others require two or more drugs to get the desired effect. When this happens, patients may forget or dislike taking several pills, and so there is a chance that blood pressure remains uncontrolled. For these reasons, it can be desirable to combine several drugs into a single pill. This is the reason why researchers have developed the study drug.

The study drug is a single capsule containing three drugs: amlodipine, bisoprolol and perindopril. Each of them is already marketed to treat high blood pressure and other heart diseases. Each one is available as a separate tablet. This study is called a phase 3 study. The aims of the study were to see:

- how the study drug and the 3 separate tablets are effective for treating high blood pressure.
- how safe the study drug and the 3 separate tablets are.

### 2 When and where did this study take place?

#### When did the study take place?

- This study started in May 2018.
- It ended in December 2018.

#### Where did the study take place?

The study took place in the Russian Federation.

### 3 Who participated in the study?

#### Which participants were included in the study?

To take part, participants had to be:

- 18 years of age or older.
- diagnosed with uncontrolled high blood pressure despite undergoing treatment. Uncontrolled means that:
  - the systolic blood pressure was between 140 and 160 mmHg.
  - the diastolic blood pressure was between 90 and 100 mmHg.

#### How many participants took part in the study?

A total of 150 participants took part in the study: 87 women and 63 men.

#### How old were the participants?

The average age of the participants was 55 years. The youngest participant was 33 years old and the oldest was 77 years old.

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### 4 Which treatments did the participants receive?

Patients received either:

- one single capsule of a fixed dose combination of amlodipine 5mg/bisoprolol 5 mg/perindopril 5 mg (study drug), or
- 3 separate tablets, called a free combination (one tablet of amlodipine 5 mg + one tablet of bisoprolol 5 mg + one tablet of perindopril 5 mg taken at the same time).

Patients took the treatment once a day in the morning.

### 5 How was the study carried out?

The study is called an “open-label” study. This means that both the participants and the research doctors knew which treatment was taken.

The study was a “randomised” study. It means that patients were put by chance into one of 2 groups.

Among the 150 participants included in the study

- 77 participants took the single capsule.
- 72 participants took the free combination.

One participant was finally not able to carry on the study as planned and so was withdrawn from the study.

The participants took the treatment for 12 weeks.

The participants visited the doctors regularly. During the visits, the doctors collected information about the participants’ health and measured the blood pressure.

Participants whose blood pressure was still not controlled (at 2 consecutive visits) had to stop the treatment.

### 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 the single capsule or the free combination of 3 separate tablets.

The results may be presented differently in other documents related to the study.

The table below shows the number of participants who had side effects.

	Single Capsule (out of 77 participants)	3 Separate Tablets (out of 72 participants)
Participants who had side effect(s)	1 (1.3%)	5 (6.9%)
Participants who had serious* side effect	0	0
Participants who stopped the treatment because of side effect(s)	0	1 (1.4%)













*\*See definition of serious side effects below*


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### What were the side effects?

The table below shows the side effects reported in the study.

	Single Capsule (out of 77 participants)	3 Separate Tablets (out of 72 participants)
Type of heart rhythm disorder (sinusoidal block)	1  (1.3%)	0 
Low blood pressure	0 	1  (1.4%)
Dizziness or light headedness when standing up because of a drop in blood pressure	0 	1  (1.4%)
Slow heartbeat	0 	1  (1.4%)
High blood potassium level	0 	1  (1.4%)
Joint swelling	0 	1  (1.4%)

 = participants

### What were the serious side effects?

A side effect is considered serious when:

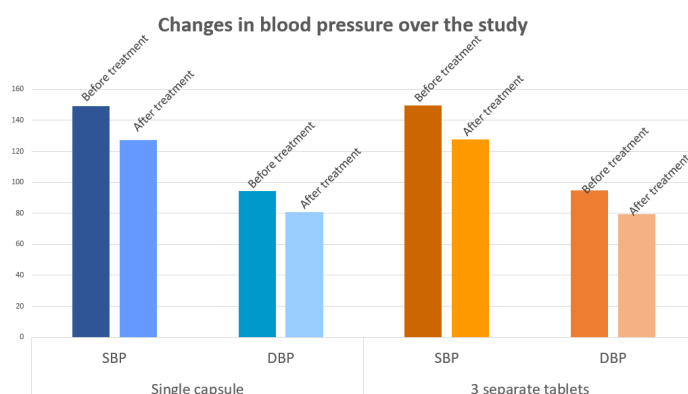
- the participant needs to be hospitalised,
- it causes lasting damage or death,
- the participant's life is in danger or,
- it is medically important in the doctor's opinion.

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

### 7 What were the study results?

The study was completed as planned.

This document presents only the results of the changes in blood pressure over the study. Other results are available in other documents listed in section 10.



The study found that the single capsule (study drug) and the 3 separate tablets improved the blood pressure over the three months.

The study drug (single capsule) and the 3 separate tablets were well tolerated. The safety was in line with what is already known for the 3 separate tablets.

### 8 How has this study helped research?

This study helped researchers to gather more information on the treatment of participants with high blood pressure.

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

### 9 Are there plans for further studies?

No other studies with the study drug are planned so far.

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## 10 Further information

### What are the identification numbers of the study?

- Protocol code: CL3-05166-003
- US NCT number: NCT05288400

### Who did the study?

The company that organised and funded the research, called the “sponsor”, is Les Laboratoires 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/>
- [www.clinicaltrials.gov](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/>