About the study

High blood pressure (hypertension) is a condition where the force of blood in your blood vessels is too high. This can lead to serious problems like heart attack and stroke.

By taking part in this study, you will help researchers understand the effectiveness and safety of the investigational study drug for adults with high blood pressure.

The goals of the study are to:

- Understand how safe and effective the study drug is at lowering blood pressure when compared to the placebo (inactive medicine).
- Find the best dose that works well and is well-tolerated.

You may be eligible if you:

- Are a male or female 18 to 75 years of age.
- Are not taking blood pressure medicine(s)

OR

Are taking up to 2 blood pressure medicines and can safely stop taking them for about 4 months

Your health will be closely monitored in case you need blood pressure medicine(s) during the study.



Thank you for your interest in the CQCZ484A12201 Study.

Clinical studies help doctors find new ways to treat medical conditions. These studies explore whether a study drug works safely in people with that condition.

You may or may not directly benefit from being in this study. Information learned through your participation will help the development of this study drug and its availability to others with high blood pressure in the future.

Being in a clinical study is your choice. If you decide to join and then change your mind, you can leave at any time.

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The CQCZ484A12201 Study

A clinical study for adults with high blood pressure (hypertension)

Study Overview



What happens during the study?

The study lasts about 1.5 years with about 20 visits. The study is divided into 3 periods.

1. Screening Period:

(about 1 month)

To see if you qualify, you will answer questions about your health and have tests. If you take blood pressure medicine(s), you will be asked to stop taking them. Your Study Doctor will help determine if you can do this safely.

2. Study Treatment Period:

(about 12 months)

This period has 2 parts, each lasting 6 months and with about 16 total visits. Some visits may take place over the phone. Everyone who qualifies for the study will have a chance to receive the study drug. (This is explained more in the next section.)

3. Follow-up Period:

(about 6 months)

After completing the Study Treatment Period, you will have 2 more study visits to check on your health.

At the end of the study, you may have a chance to continue receiving the study drug through an extension study.

What study treatment will I receive?

During **Part 1** of the Study Treatment Period, you will receive either the study drug or the placebo (inactive medicine).



The placebo helps researchers understand the true effects of the study drug. You have a greater chance of receiving the study drug than the placebo.

If you received the placebo in Part 1, you will receive the study drug during **Part 2.**

If you received the study drug in Part 1, you will receive either the study drug or the placebo in Part 2.

You will receive the study drug or the placebo as an injection (shot) under the skin every 6 months.

You will need to stop taking any other blood pressure medicine(s) for up to 4 months during the study. This allows researchers to understand the effects of the study drug on its own. Your health will be closely monitored in case you need additional blood pressure medicine(s).



What study health checks and tests will I have?

Below are some tests you will have at study visits. You will not have every test at each visit.







Checkup

Pulse rate

Blood pressure monitoring







Blood tests



Urine tests



(ECG)

Side effects and safety check

Blood pressure monitoring

At specific times during the study, you will:

- Have your blood pressure measured at the study site.
- Wear a device that monitors your blood pressure for 24 hours.
- Use a device to check your blood pressure at home.

ECG = electrocardiogram.