



## Who is taking part in the 1378-0005 Clinical Study?

Approximately **550 participants** in around **200 study sites** across **North and South America, Europe, Asia, Africa and Australia** are expected to take part. You may be able to take part if you:

- Are 18 years of age or older
- Have diabetic or non-diabetic CKD
- Are currently receiving medication for your condition

There are other criteria that you will need to meet to qualify, which the study team will discuss with you.



## Why should I take part?

A clinical research study is an important step towards finding potential future treatments for people with CKD. If you decide to take part, you'll be helping researchers understand your disease better and playing an important role in ongoing efforts to improve healthcare.



## Want to know more?

If you would like to learn more about the **1378-0005 Clinical Study**, contact:

Name: .....

Study site: .....

Address: .....

.....

Telephone: .....

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Email: .....

.....

Contacting us does not mean that you must join the study or that you will be able to participate.

# Help us break the cycle of **chronic** kidney disease

## Information Brochure

**1378-0005**  
CLINICAL STUDY

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## What is clinical research?

The aim of clinical research is to help people live longer, healthier lives. To achieve this, researchers develop drugs that improve the treatment and prevention of diseases. Testing of investigational drugs takes place in clinical studies.



## What is the 1378-0005 Clinical Study?

The **1378-0005 Clinical Study** is testing an investigational drug, called **BI 690517**, to see whether it could help people with **chronic kidney disease (CKD)**. BI 690517 will be tested on its own and in combination with another drug, called **empagliflozin**.



## What are BI 690517 and empagliflozin?

BI 690517 is designed to block production of a hormone that has an influence on kidney function, called **aldosterone**. Researchers believe that reducing aldosterone levels could improve kidney function and slow disease progression. Empagliflozin works by causing glucose to be excreted in urine. It is already approved to treat type 2 diabetes and has recently been shown to have beneficial effects on the heart and the kidney.



## What happens during the study?

Participation in the **1378-0005 Clinical Study** could last up to **29 weeks** and consists of **4 parts**:

- **Part 1: Screening (up to 3 weeks)** – If you are interested in taking part, you will be invited to a study site near you to have medical tests and assessments.
- **Part 2: Run-in (8 weeks)** – If eligible, you will receive **background medication** of either empagliflozin or placebo. A **placebo** contains no active medication.
- **Part 3: Study treatment (14 weeks)** – You will then receive **1 of 3 doses** of either BI 690517 or placebo, in addition to your background medication taken during run-in.
- **Part 4: Follow-up (4 weeks)** – After your last dose, you will have more tests to see how you are responding to the study drugs.



## Which study drugs will I receive?

During the run-in period, you will have a **50% (1 out of 2)** chance of receiving empagliflozin and a **50%** chance of receiving placebo. During the study treatment period, you will have a **75% (3 out of 4)** chance of receiving BI 690517 and a **25% (1 out of 4)** chance of receiving placebo.



## How do I take the study drugs?

BI 690517, empagliflozin and placebo are supplied as tablets. During the run-in period, you will take **1 tablet** of either empagliflozin or placebo daily. During the study treatment period, you will take **1 tablet** of either empagliflozin or placebo daily and **3 tablets** of either BI 690517 or placebo daily (**4 tablets in total**).



## What happens at study visits?

During the study, you will be expected to attend up to **12 visits**. Visits will take place at the study site, your home or via phone/video call. At each visit, you will have tests to check on your health and to see how you are responding to the study drugs. Tests include:

- Collection of blood and urine samples
- Physical examination
- Electrocardiogram (ECG), which measures the electrical activity of your heart



**Throughout the study, you will also be asked to collect samples of your urine at home.**