

STOP-PKD Study

Simple Information for Patients with ADPKD

What is the STOP-PKD study

In recent years, several large studies have shown that some drugs called **SGLT2 inhibitors** play an important role in treating people with kidney disease. They help to slow down the loss of kidney function, are generally well tolerated and are very affordable.

These medications are already safely used in people with type 2 diabetes, heart failure, and other kidney diseases. However, previous clinical trials did not include people living with **ADPKD**. Small earlier studies suggest that **SGLT2 inhibitors may also help people with ADPKD to retain their kidney function for longer**.

The aim of this new international study (involving 27 hospitals and enrolling a total of 420 people) is to carefully test this in a larger group of ADPKD patients, to find out whether the medication could truly help people affected by this condition.



Why is this study important?

At present, there is only one approved medicine used to slow **ADPKD progression** (Tolvaptan). It is not prescribable for every patient and has some undesirable side effects for some. For this reason, **researchers are looking for additional treatment options**.



What will I need to do?

- Attend a **screening visit** to check if you are eligible to take part.
- Take the **study tablet** as instructed.
- Have **regular blood and urine tests**.
- Have your **blood pressure** and weight checked.
- Complete simple **questionnaires** about your health and quality of life.
- Some **participants will have MRI scans to measure kidney size**.



Who cannot take part?

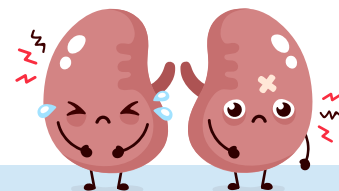
- People who have **recently been treated with certain medications** (such as Tolvaptan, SGLT2 inhibitors, Lithium, or Somatostatin analogues).
- **People affected by type 1 diabetes**.
- People with **significant liver problems**.
- People **having very high or very low blood pressure that is not controlled**.
- If you are **pregnant or breastfeeding**.
- People with **other serious medical conditions** that could make participation unsafe.

How does the study work?

- Participants are divided in **two groups**. A computer assigns each person to a group at random (this is called "**randomization**").
- One group receives the **study medication**.
- The other group receives a **placebo** (a tablet with no active medication that looks the same as the study medication and simulate its effects).
- **Neither you nor your doctor** will know which treatment you are receiving during the study (this is called "**double-blind**").
- The study will last about **3 years**.
- You will have study **visits approximately every 3 months**.

Who may be able to take part?

- **Adults aged 18 to 60 years** with confirmed **ADPKD**.
- **Kidney function between 25% and 90%**
- **Large polycystic kidneys**
- **Stable blood pressure treatment** (if already prescribed).



Your safety and your choice

Your safety is very important! **You will be closely monitored during the study**. All side effects will be carefully recorded and managed.

Taking part is **completely voluntary**. **You can decide not to participate or stop at any time**. Your regular medical care will not be affected.

If you are interested, **please speak with your nephrologist or contact a participating study centre**.