Participation in a clinical research study is completely voluntary. Before a study volunteer enters a study, a study doctor will discuss the details of the study. These details include information about the investigational drugs, what happens during the study, and any potential risks or side effects.

The purpose of clinical research is to:

1. Answer specific health questions
2. Evaluate the safety and effectiveness of investigational drugs
3. Discover potential new ways to improve health and/or disease symptoms

Thank you for considering the Sjögren’s syndrome clinical research study.

For more information, or to see if you might qualify, please contact:

Phone: (270) 769-2535, Ext 4

Center for Arthritis and Osteoporosis
584 Westport Road Suite 101
Elizabethtown, KY  42701

Disclaimer: filgotinib, GS-4059 (tirabrutinib), and GS-9876 are investigational drugs whose safety and efficacy have not been demonstrated.
Sjögren’s syndrome is a disease that causes the body’s immune system to attack its own healthy cells. This can affect tear ducts around the eyes or saliva glands in the mouth, causing dry eyes and dry mouth. Along with symptoms of dryness, patients may have stiff joints, skin rashes, and feel very tired. The condition can also affect other parts of the body such as the kidneys, liver, or lungs. Sjögren’s syndrome may be more than just annoying symptoms—it can affect your quality of life.

Currently, there are few therapeutic options available to relieve the symptoms of Sjögren’s syndrome. This clinical research study will evaluate three different investigational drugs to see if they are safe and effective for Sjögren’s syndrome.

What should I know about the study drugs?

In autoimmune diseases such as Sjögren’s syndrome, the immune system becomes activated, causing it to mistakenly attack healthy tissue. Activation of some of the immune cells depends on messaging proteins within the cells. Filgotinib, GS-9876, and GS-4059 (tirabrutinib) are investigational drugs that may inhibit these messaging proteins. Researchers want to find out if these study drugs are safe and effective for Sjögren’s syndrome.

What does the study involve?

Before you start taking any of the study drugs, you will attend a screening visit to make sure that you are a good fit for this study. You will have several health procedures done, including blood and urine tests, breathing tests, and an electrocardiogram (ECG).

- This study will consist of one screening visit and at least 14 study center visits.
- The visits are about two to six weeks apart for about 52 weeks, or about one year.

If you are eligible to participate and you agree to take part in the study:

- During the first 24 weeks of the study, you will be assigned randomly to one of four groups:
  - Receive filgotinib investigational drug
  - Receive GS-9876 investigational drug
  - Receive GS-4059 (tirabrutinib) investigational drug
  - Receive a placebo (dummy drug)
- After 24 weeks in the study, participants who were placed into the placebo group will be moved randomly to a group that will receive one of the three investigational study drugs.

- Neither you nor the study doctor will know which study drug, if any, you will receive.
- No matter which group you are in, you will take three tablets every day.

Why should I participate?

Participants may:

- Try an oral investigational drug to see if it may be beneficial for Sjögren’s syndrome
- Receive study drug and study-related care from a local study doctor at no cost
- Receive reimbursement for study-related travel expenses

Could I qualify?

You may qualify for this study if you:

- Are between 18 and 75 years old
- Have been diagnosed with active Sjögren’s syndrome
- Do not have tuberculosis (TB)

Additional eligibility requirements apply. Study participation is voluntary, and you may stop participating in the study for any reason at any time.

What are clinical studies?

A clinical research study is carefully supervised research done with people before an investigational drug is made available to the public. Each study is performed according to government regulations, which help protect the safety and rights of study participants.