If chronic rhinosinusitis with nasal polyps is causing loss of smell, congestion, runny nose, or facial pain/pressure, you may want to consider a clinical study for adults 18 to 65 years of age. Ask your doctor about the TITAN study.
Why is this study important?

This study is important because it will test how well a study drug works on nasal and sinus symptoms related to chronic rhinosinusitis (persistent swelling of the nasal and sinus passages) for patients with or without nasal polyps (soft growths in the nasal passages). This study will also find out if this study drug is safe.

Even if the study drug does not help you, the results of the study may help others in the future. Pharmaceutical companies use clinical research studies like this one to learn more about investigational medications before they are made available to the public. Study volunteers can help us in this important research. Thank you for considering participation in this trial.

What is the purpose of this study?

The purpose of this research study is to:

- Test the safety of the study drug (called GB001)
- Find out if GB001 helps decrease symptoms of chronic rhinosinusitis such as stuffy nose or loss of smell
- Check how much of the study drug gets into the bloodstream and how long the body takes to get rid of the drug

Who can participate in this study?

To be eligible for this study, you must be:

- 18 to 65 years of age
- Diagnosed with chronic rhinosinusitis with or without bilateral nasal polyps
- Able to give informed consent

This is not a complete list of study requirements. The study doctor will review the full criteria for this study with you.

How long will the study last?

Your participation in this study will last about 24 weeks and will include around 8 study visits to the study center.

What are my costs to take part in this study?

You do not have to pay for the study drug, study supplies, study visits, or tests that are part of the research study.

What risks are involved if I decide to participate?

There are possible risks involved with any clinical study. Your study doctor will review the risks with you, and you will be closely monitored throughout the study. Since the study drug GB001 is investigational, there may be risks that are unknown. Tell your doctor if you have any symptoms. There also may be unknown risks to a pregnancy, embryo, or fetus (unborn baby) if you become pregnant.

What can I expect if I decide to participate?

If you enroll in this study, you will be randomly assigned by chance (like the flip of a coin) to receive either GB001 or placebo. You will have a 50% (1 in 2) chance of receiving GB001 or placebo. This is a double-blind study, which means neither you nor the study doctor will know which of these study drug groups you are assigned.

Every day, you will take 2 tablets of the study drug (either GB001 or placebo) by mouth. If you were taking a different intranasal corticosteroid medication than mometasone furoate nasal spray (MFNS) before starting this study, you will be switched over to MFNS. You will continue to use the MFNS as directed by your study doctor.

You will also be trained on how to use a daily diary to record your nasal symptoms, MFNS doses, and study drug doses.

If you participate in this study, you will be expected to:

- Attend each visit.
- Take the study drug and MFNS as expected.
- Complete your diary and bring it back to the study center.
- Return any unused study drug and the bottles that it comes in.
- Report on how you have been feeling while on the study.

Lab tests, a physical exam, and other assessments and questionnaires will be conducted at the in-clinic visits. Not all activities will occur at every visit.