



About Clinical Research

Clinical research studies are required by the US FDA (Food and Drug Administration) to test all medications before they are made available to the public. These studies help researchers determine the effects of an investigational medication and decide if it is safe for people to use.

All clinical research studies must follow rules set by the government. These rules protect the safety and rights of the participants in the clinical research study, while information is collected about the safety and effectiveness of the investigational medication.

Participating in a clinical research study is an important decision and should be thought through carefully. Participation is voluntary. You have the right to withdraw from the study at any time, for any reason. You will keep the right to the same conventional therapy you received before.

You do not have to participate in this clinical research study to receive conventional therapy. The study doctor will discuss all treatment options that may be available to you.



Want to Know More?

If you would like to learn more about this study, please ask your healthcare provider for more information or contact the study doctor at the number below:

Clinic Name:

Contact Person:

Address:

Telephone:

Or visit the CIC Study website at www.CICStudy.com

Does chronic constipation limit your life?



A clinical research study evaluating the safety and effectiveness of an investigational medication for individuals with **chronic constipation** is currently seeking volunteers.



SYNERGY PHARMACEUTICALS INC.





What is Chronic Constipation?

Constipation is a condition in which bowel movements become difficult or less frequent. A person is considered to have chronic constipation after symptoms have lasted for 3 or more months. Though it can be difficult to talk about, chronic constipation is a serious medical condition that may greatly affect a person's quality of life by limiting daily activities and the ability to work.

If you have suffered from some or all of the following symptoms for 3 or more months, you may have chronic constipation:

- Fewer than 3 bowel movements per week
- Feeling of incomplete bowel movements
- Straining while having a bowel movement
- Lumpy or hard stools
- Bloating, discomfort or pain in your abdomen

Currently, there is no cure for chronic constipation. Instead, the condition is managed by treating the symptoms through lifestyle changes such as a high fiber diet, regular exercise and increased fluid intake. Sometimes over-the-counter products such as laxatives and stool softeners may be prescribed. However, often these treatments are not effective in managing the symptoms of chronic constipation.



What is the CIC Study?

The purpose of the CIC Study is to determine the safest and most effective dose of an investigational medication for individuals with chronic constipation. The CIC Study will look at whether the investigational medication increases the number of bowel movements and decreases other symptoms, such as bloating and discomfort, in people with chronic constipation.

The CIC Study will enroll 880 men and women with chronic constipation in approximately 110 study centers across the United States.

The investigational medication being studied is plecanatide. Plecanatide produces an increase in the amount of fluid inside the intestines, making bowel movements easier. It works in a way that is similar to a natural product normally present in the body.

Participants will be randomly assigned (like flipping a coin) to receive either the investigational medication or a placebo. The placebo looks like the investigational medication, but contains no active ingredients. Participants will have a 75% chance of receiving the investigational medication and only a 25% chance of receiving placebo.



Your Role in the CIC Study

You may qualify for the CIC study if:

- You have chronic constipation
- You are 18-75 years of age (male or female)

Other criteria must be met to participate and will be determined at the study center. If you decide you would like to participate, you will first be asked to participate in a screening and pre-treatment period in order to determine if you meet all of the entry criteria for the study. If you qualify, you will enter a 12-week treatment period during which you will be given the investigational medication (plecanatide) or placebo. Total participation in the CIC study will last approximately 16 weeks and will involve about 6 office visits.

Your participation is completely voluntary. If you do not decide to participate, you will keep your right to the same conventional therapy you received before participating in this study. Your study doctor will discuss with you any other treatments that may be helpful to you.

If you qualify for the CIC study, you will receive at no cost:

- Investigational medication or placebo
- Close medical attention and monitoring of your condition
- Study-related physical exams
- Study-related tests