About Ulcerative Colitis

Ulcerative Colitis (UC) is a lifelong condition that can seriously affect quality of life. It is a chronic, relapsing disease marked by inflammation and ulceration of the colon. Many people experience symptoms of rectal bleeding, lower abdominal pain, and diarrhea. At times, these symptoms may subside but at other times, they may worsen.

You may qualify to participate in a clinical research study of a new investigational medication.

About Clinical Research

A Clinical research study is an evaluation of an investigational study medication given to study volunteers to obtain information to determine whether the investigational medication is safe and effective in treating certain medical conditions or disorders. The investigational medication must have been tested in animals for safety before it is used in a clinical research study involving human subjects. In this clinical research study, the participants are patients that have moderate to severe UC.

All participants in a clinical research study are closely monitored by the study doctors who are specialists in their field.

At the end of the study, the results obtained from the participants will be analyzed in details. This helps the study sponsor and regulatory authorities determine whether or not the investigational medication is safe and is able to treat the disease of moderate to severe UC.

TUSCANY
B7541002

To find out more information about this clinical research study for Moderate to Severe Ulcerative Colitis, please contact:

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You may have another option

New Clinical Research Study for Moderate to Severe Ulcerative Colitis

If you are living with ulcerative colitis and trying to manage the symptoms, you may be interested.

Take a look inside for more information.

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Study B7541002 – New Clinical Research Study for Moderate to Severe Ulcerative Colitis

B7541002 TUSCANY is a multi-center international clinical research study which is underway to evaluate the treatment and safety of a new investigational medication given to patients suffering from moderate to severe Ulcerative Colitis and who have failed or have been intolerant to at least one conventional therapy for their condition.

Study doctors are seeking qualified individuals to participate in this clinical research study. Qualified study participants must be

- Male or female,
- 18 to 65 years of age,
- and have a positive histological diagnosis of ulcerative colitis.

Additional eligibility criteria apply. These will be explained to you and your questions will be answered when you contact the person listed at the contact number provided in this brochure.

Participation in this clinical research study involves visiting the study doctor for a total of 15 scheduled appointments over 26 weeks, which includes a 14 week treatment period. You will receive a total of 7 doses of investigational medication intravenously. After the treatment period you will be REQUIRED to visit your study doctor for 5 visits in a 3-month follow-up period. No investigational medication will be given to you in this period.

Study-related examinations and health assessments will be performed at each study visit and you will be asked to complete an electronic diary to record the number of stools per day and any rectal bleeding.

Study FAQs

Following are some frequently asked questions about clinical trials.

What are the benefits and risks of participating in a clinical research study?

By participating in this clinical research study, it is possible that your condition or health may improve if given the investigational medication or because you are monitored closely throughout the study during the study visits. Information gathered from this study may also help other people in the future.

There may also be risks experienced when participating in a clinical research study. Negative side effects, which may vary from person to person, could occur. Also, the investigational medication may not be helpful to you.

How are my rights protected if I decide to participate in a clinical research study?

An institutional review board (IRB) or independent ethics committee (IEC) helps to protect the rights of study participants. The individuals who make up the IRB or IEC are not associated with the study sponsor or design of the clinical research study. Their function is to review the study to help ensure the rights of the study participants. They also ensure that study participants are well informed about the study and about their rights by reviewing and approving the informed consent material that each study participant receives and signs before any study procedures are performed.

How much does it cost to participate in this clinical trial?

Study medication and study-related examinations and procedures are provided at no cost. Qualified participants may be eligible for reimbursement for travel.

What else can I expect if I participate in a clinical study?

An informed consent document will be given to you which includes information about the clinical study, as well as potential benefits and possible risks associated with the research. You should carefully consider, and talk with your doctors and family about, both the potential benefits and risks of participation before enrolling in a clinical study.