

Chronic Pancreatitis Research Study

Have you been diagnosed with Chronic Pancreatitis?

We are currently working on a research study using an Investigational drug that is being evaluated to treat patients who have been diagnosed with Chronic Pancreatitis (CP).

The purpose of this study (double-blind phase) is to determine how well the Investigational drug works in controlling pain associated with this disease; determine the pharmacokinetics (PK) (drug levels of the Investigational drug); and how safe the drug is when taking one of three doses of NI-03 (100 mg, 200 mg and 300 mg) three times daily for 28 consecutive days (4 weeks) compared to placebo (sugar pill) also taken in the same manner.

To be eligible for this study, you must meet the following criteria and others not mentioned below:

- Adults age 18-85 with a diagnosis of CP established by an imaging study, such as Endoscopic Ultrasound or CT/MRI scan
- Able to complete 6 visits over a 10-week period, with 2 visits lasting approximately 5 hours each
- No significant medical condition that would impose a risk to you or that would interfere with the results of the study
- No present illness of infection within the past 30 days
- Opioid analgesic regimen that is stable and less than 100mg morphine equivalent/day
- Not pregnant, planning to become pregnant and agree to use acceptable contraception while on the study

If you are eligible for this study, you will receive the following at no cost to yourself:

- Appointments with study doctors and nurses who will answer any questions you may have about the study
- Study-related physical exams, blood work and other tests that will be performed as part of your participation in the study
- Investigational study drug
- Reimbursement for travel costs

Participation in a clinical study is voluntary.

You have the right to ask questions and to be fully informed about any risks and benefits to you by participating in the study.

You have the right to withdraw from the study at any time, for any reason, without penalty or loss of benefits to which you are otherwise entitled.

This study is currently being conducted at:

***West Michigan Clinical Research Center
2093 Health Drive SW, Suite 201
Wyoming, MI 49519***

V20OCT2017

This study is being sponsored by:

KC Specialty Therapeutics, LLC

and



Call today to see if you may qualify for this important study!

Your participation and health related information obtained in a clinical trial is confidential – your information will not be shared with anyone who is not affiliated with the study.

For more information about the study and to see if you qualify, please contact:

***West Michigan Clinical Research Center
(616) 328-5344
www.wmcrc.com***

APPROVED: Oct 23, 2017
COPERNICUS GROUP IRB