



Every day,

research uncovers new information about medical conditions and their treatment. Volunteer involvement in clinical studies, especially for rare diseases, is a crucial step in the development and advancement of potential future therapies. Results collected from clinical studies have led to new and better medications becoming available to patients all over the world.

Why should I participate in the SORENTO study?

Better and more convenient treatment options for GEP-NET are needed to improve patient care. This study will contribute to the development of a potential new treatment. Participants will also receive medical monitoring throughout the study that may provide additional health insights.

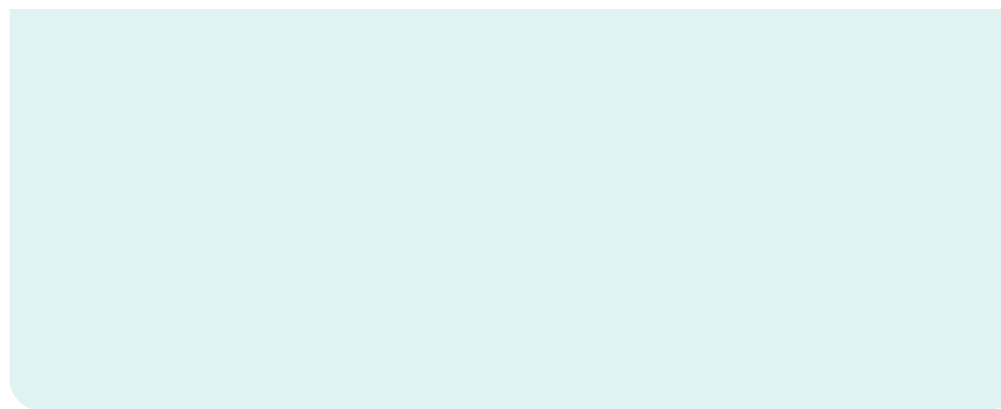
Taking part in a clinical study is completely voluntary. If you enroll, you can choose to leave the study at any time and for any reason and it will not affect your usual care.

Will this study cost anything?

You will not have to pay for the study drug, study visits, or for the procedures needed for you to take part in this study. The sponsor of the study will pay for the costs of the study drug, as well as the costs of the tests and procedures needed in this study. You may also be reimbursed for study-related travel expenses (such as parking, bus fare, etc.). The Informed Consent Form or the study staff can tell you more.

How can I learn more about the SORENTO study?

To ask questions or find out if you could participate, please contact:



Thank you for considering participation in this clinical study. With your help and the help of other volunteers, we can work together to further the development of potential new treatments for people with advanced gastroenteropancreatic neuroendocrine tumors (GEP-NET).

Take part in a study of an investigational GEP-NET treatment you take at home.



A new formulation of octreotide with self-administration

SORENTO™

Subcutaneous Octreotide Randomized Efficacy in Neuroendocrine Tumors



What is a clinical study?

A clinical study (also known as a clinical trial) is designed to learn more about a drug's ability to treat a specific disease or condition. Regulatory agencies and health authorities such as the U.S. Food & Drug Administration (FDA) and the European Medicines Agency (EMA) use the results of clinical studies to decide if a drug should be approved to be prescribed to patients. Many drugs used in clinical studies have not yet been approved for the treatment of a disease and are being tested to see if they should be approved as a future treatment option.

Clinical studies are conducted by experienced and trained medical professionals who monitor participants throughout the study. Also, every clinical study is reviewed by a regulatory health authority and an institutional review board (IRB) or ethics committee (EC), which helps ensure that the study is conducted properly and that the rights of study participants are protected.

What is GEP-NET?

GEP-NET stands for gastroenteropancreatic neuroendocrine tumor. This is a rare type of tumor that starts in the pancreas, stomach, small intestine, rectum, colon, appendix, or other areas of the gastrointestinal tract. Currently, the recommended standard of care for many patients with GEP-NET is to be treated with somatostatin analogues (SSAs).



Clinical studies are the only way we can develop new and better cancer treatments and improve patient care.

What is the purpose of the SORENTO study?

SORENTO stands for “**Subcutaneous Octreotide Randomized Efficacy in Neuroendocrine Tumors.**” The purpose of the SORENTO study is to compare the efficacy of an investigational drug to already approved SSAs, octreotide long-acting release (LAR) or lanreotide autogel (ATG), in people with advanced GEP-NET.



What are the drugs being used in this study?

The investigational drug being tested in the study is called CAM2029, which is a long-acting investigational formulation of octreotide. CAM2029 is provided in either a ready-to-use syringe or pre-filled pen that can be administered subcutaneously at home by you or a caregiver.

The comparator drugs used in the study are octreotide LAR and lanreotide ATG. Both of these drugs are approved in your country for the treatment of GEP-NET. The products containing these two formulations may be sold under different brand names in your country (such as Sandostatin LAR or Somatuline). These comparator drugs must be administered by a nurse or doctor at a clinic or hospital.

Who can be in the SORENTO study?

To take part, you must:

- Be 18 years of age or older
- Have advanced (unresectable and/or metastatic) GEP-NET
- Not have GEP-NET that has spread to the brain or central nervous system or progressed after previous treatment (refractory)
- Not have been treated with long-acting SSAs for longer than 6 months

These and other criteria will be reviewed by the study doctor to find out if you are eligible for the study.

What does it mean for me to participate in this study?

Approximately 300 people will take part in this study at research sites in North America and Europe. The study is divided into several parts:

- **Screening:** Your medical history will be reviewed, and other tests will be done to see if you can take part in the study. This process may take up to approximately 1 month.
- **Randomized Treatment Period:** If you qualify, you will be randomly assigned (like flipping a coin) to one of two different study treatment groups with **either** CAM2029 (every 2 weeks) or one of the comparator drugs (every 4 weeks). Participants in both groups will continue study treatment until their GEP-NET gets worse (called “disease progression”) or as advised by the study doctor.
- **Extension Period:** If your GEP-NET gets worse, you will have the option of starting study treatment with CAM2029 every week, regardless of which treatment group you were assigned when randomized. This period will then continue until your GEP-NET progresses. If you choose not to enter the extension period, you will proceed directly to the Safety Follow-up Visit.
- **Safety Follow-up Visit:** You will return to the study clinic 1-2 months after the end of study treatment (either from Randomized Treatment Period or Extension Period) to check on your health. All study participants will attend this visit.
- **Efficacy Follow-up Period:** If your study treatment ended for reasons other than disease progression, you will come to the study clinic every 12 weeks after the Safety Follow-up visit for tumor assessments and to check on your health.
- **Long-term Follow-up Period:** After the end of all other study periods, study staff will continue to contact you by phone every 12 weeks for as long as planned by the study to check on your health.

Screening	Randomized Treatment	Extension (optional)	Safety Follow-up	Efficacy Follow-up	Long-term Follow-up
Up to 1 month	CAM2029 or Comparator Drug	only CAM2029	1-2 months after study treatment ends	Study visit every 12 weeks	Phone call every 12 weeks

Procedures at study visits may include tumor imaging (MRI or CT scans), PET scans, gallbladder ultrasounds, blood draws, height and weight measurements, vital signs, bone scans, ECG, and questionnaires.