Gastroparesis making you miss pieces of your life?

Learn more about the avanzar study.

Information for potential participants.

avanzar

A Research Study for Adults with Diabetic or Idiopathic Gastroparesis

Nausea, vomiting or feeling full quickly after eating?

If you have gastroparesis and you experience nausea, vomiting or belly pain after meals, sitting down to a meal might not always be a joyful experience. This means you may need a different approach to your gastroparesis treatment.

"Investigational" means that the drug being tested has not yet been approved for sale.

Gastroparesis is a condition in which the muscles in the stomach work slower than usual, which can lead to symptoms such as nausea, vomiting, feeling full quickly after eating or belly pain. Presently, there is no cure for gastroparesis and options to treat symptoms and improve quality of life are limited. The few medical and surgical options available have been limited by their potential side effects and so are not suitable for long-term use.

Many people don't understand how debilitating the condition can be. But we do. The **avanzar** study will assess the safety and effectiveness of an investigational study medication in treating the symptoms of gastroparesis caused by diabetes (diabetic gastroparesis) or an unknown factor (idiopathic gastroparesis).

If you have diagnosed or suspected gastroparesis (diabetic or idiopathic) and are between 18 and 85 years of age, you may be able to take part in the **avanzar** clinical research study. This leaflet will tell you a bit more about the study and what it involves.

What is a clinical research study?

Clinical research studies are highly regulated research studies performed to detect, diagnose, treat and prevent disease. Without them, we would not have vaccines that prevent common illnesses, antibiotics to treat infections, over-the-counter pain medicines, tests that detect cancer, or devices that regulate heartbeats – to name a few.

Every clinical study must be approved and monitored by an Institutional Review Board or Ethics Committee to make sure the risks are as low as possible and that the rights of participants are protected. All study participants have the right to discontinue participation and leave the study at any time and for any reason, with no penalty or loss of benefits to which they are otherwise entitled.

What's involved in participating?

Screening Period

5 weeks

To assess participants' suitability for the study

Treatment Period

12 weeks

Participants will receive study treatment and their health will be monitored via regular clinic visits

Follow-up Period

Lasts for 40 days after last dose of study medication

To monitor for any lasting effects

In total, study participation will last for approximately 22 weeks.

What study treatment will I receive?

At the start of the treatment period, participants will randomly (by chance) receive either:

- The investigational study medication, at one of three doses (a 75% chance)
- A placebo (a 25% chance)

The placebo looks like the investigational study medication but does not contain any active ingredients. It is used to compare with the results of the study medication. Neither you nor the study doctor will know which group you are in.

How will I take my assigned study medication?

You will be asked to take one capsule of your assigned study medication (either the investigational study medication or the placebo) in the morning before breakfast, and one capsule in the evening before dinner, every day.

How will my health be monitored?

If you take part in the study, you will need to visit the study clinic about seven times so that we can monitor your health. Health assessments will vary between visits, but may include blood samples, reviewing a take-home symptom diary, completing breath tests to see how efficiently your body digests food, and answering questionnaires.

What are the risks and benefits?

There are risks and benefits to every clinical study. Your health may get better, it may stay the same, or it may get worse. While the study doctors will watch you closely, it is very important you inform the study team if you experience any significant changes (good or bad) while participating in the study. The risks and benefits of participation are outlined in detail in the Informed Consent Form (ICF) that you must read and sign before you can take part.

What else should I know?

The study medication and assessments will be provided at no cost to participants. Travel reimbursement may also be provided.

It's important to remember that you are free to leave the study at any time, for any reason, and return to your usual healthcare. We just ask that you schedule a visit so we can perform a final check on your health and safety.

If you think you may be interested in taking part in this study, or would simply like more information, please contact the study team – they will be more than happy to help. **Please be assured that asking for more information in no way obligates you to take part in the avanzar study.**