

PRINCIPAL INVESTIGATOR: Jack A. Yanovski, MD, PhD

STUDY TITLE: Phase II Trial of Liraglutide (Saxenda(R), Novo Nordisk) in Adolescents with Obesity After Sleeve Gastrectomy: A Pilot Open-Label Study

STUDY SITE: NIH Clinical Center

Cohort: Assent

Assent Version: 11/15/2021

WHY ARE YOU HERE?

We are asking you to take part in a research study of a study drug. This is because you still have a high body weight after you had sleeve gastrectomy surgery to help reduce your weight. High body weight can cause complications like diabetes (high blood sugar), high blood pressure, and high cholesterol level

Before you decide if you want to be in this study, we want to tell you about what is involved. This is so you can ask questions.

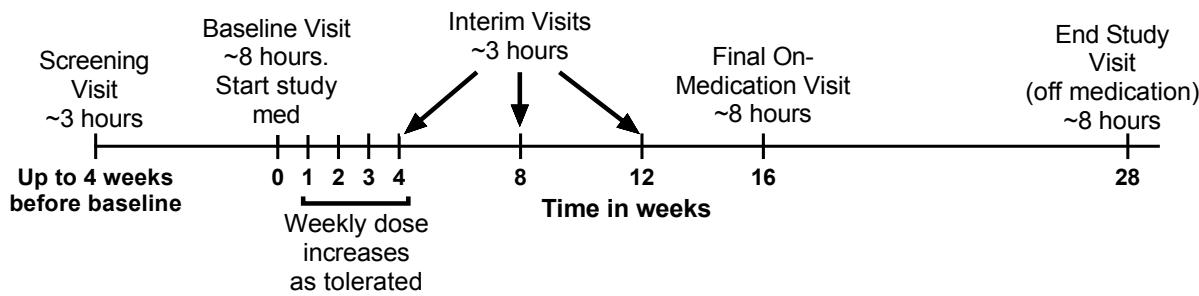
Read this paper and ask us questions about anything you do not understand. If you want to read more about the study, ask for a copy of the form that your parent will read and sign.

WHY IS THE STUDY BEING DONE?

The study is being done to see how safe the study drug is and how well it works. The study drug is called liraglutide and it is given as a once-a-day subcutaneous injection. Liraglutide is approved to treat obesity in patients 12 years and older and to treat type 2 diabetes in patients 10 years and older, but it has not yet been studied as a treatment for obesity in teenagers who have had prior weight loss surgery.

WHAT WILL I BE ASKED TO DO?

This study lasts about 28 weeks (7 months). You will need to come to the NIH Clinical Center up to 7 times. It starts with a screening visit to find out if you can take part followed by 5 monthly visits to check your weight and see how you are feeling.



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Below is a list of activities that will occur during your visits:

- You will have a **fasting blood draw** at screening visit, baseline visit, and the final on-medication visit. Fasting means you can have water but can't eat or drink anything else for at least 8 hours, but preferably for 10-12 hours, before the blood draw. At two visits, you will be asked to drink a sweet drink and have more blood draws (Baseline and final on-medication visit).
- At all Visits, you will have a **medical history and physical exam**. The first one will be very complete, the rest much shorter, where if you have complaints about your body then the study doctor will check that area of your body.
- Your **vital signs**, including blood pressure, heart rate, temperature, and breathing rate will be checked at every visit.
- Your **weight** will be measured at every visit.
- The study doctor will ask you **questions** about your health, appetite, habits, physical activity, and sleep patterns at every visit. Some tests about hunger and food will be done on the computer.
- On two occasions, you will be asked to wear a small watch-like device called an accelerometer on your wrist for 2 weeks, except when taking a bath or a shower or when taking part in a contact sport. The accelerometer will need to be returned to the team.
- If you are a girl and can get pregnant, you will be asked to take a **urine pregnancy test** at every visit. If your urine test shows you are pregnant then you will have a blood test to confirm you are pregnant.
- If you want, you might also bring a little bit of your stool or poop with you to two of your visits. If you want to do this, we will give you everything you need to get the stool here to NIH.
- You will have a **DXA X-ray** test that measures your body muscle and body fat and your height will be measured (at Screening or at Baseline Visit and also at Visit 5).
- You will be **instructed to inject the study drug** every day using a small needle just under the skin (subcutaneously). This is the way people with diabetes take insulin. Most people get used to taking these shots without any problem. If you forget to take the study drug, we will ask you not to take the medicine if more than 12 hours have passed since you were supposed to take it. Just continue the once daily regimen as prescribed with the next scheduled dose. We will ask that you not take an extra dose or increase the dose to make up for the missed dose.

If you want to do our study, we will give you \$50 for the Screening and End Study visits, \$200 for the Baseline and Final End-Medication visits, and \$75 for each of the interim visits. If you want to give us a little bit of your stool (poop), we will give you \$25 for each of the two samples.

You and your caregiver will be asked questions about how you are feeling, your behavior and habits during the study.

Girls in this study should not get pregnant. If you are a girl and you have ever had your period, your doctor will discuss this with you. You will be tested to see if you are pregnant during this

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study. If you are pregnant, your doctor may tell your parents. You should not take part in this study if you don't want a pregnancy test.

CAN BAD THINGS HAPPEN TO ME FROM BEING IN THE STUDY?

You may have new feelings or problems that you have not had before. Tell your parents and tell your study doctor or study site staff if you feel sick during the study. Tell them if you no longer want to be in this study.

Some people who have taken this study medicine before had the following side effects. You too may have these side effects:

- You may find that you may have an upset stomach, feel like throwing up, or have trouble having a bowel movement.

You may also have bad effects from some of the study tests:

- You may feel a little bit uncomfortable when we measure your blood pressure with a tight armband.
- It may feel a little uncomfortable to not have anything to eat or drink for at least 10 hours before a visit.
- You may feel a little bit uncomfortable when you need to lie down on a table to have a scan of your body.
- When a needle is put in your arm to collect blood, it may hurt, cause a bruise, make you feel dizzy, or cause an infection (very rarely). A numbing cream can be used to lessen the pain.
- The study doctor or nurse will be asking you questions about how you are feeling. You may not enjoy answering these questions.
- You may find wearing the wrist accelerometer inconvenient. If irritation at the site of the wrist strap occurs, stop wearing it and contact us.
- Other tests may be slightly inconvenient but are not risky – these include giving urine and stool samples, having body measurements with a tape measure, filling out diet surveys, and eating a meal. You may feel too full or even need to throw up after you eat the meal, especially if you eat too quickly.

You may feel other bad effects not listed. You must tell your parents or legal guardian and the study doctor if you feel sick or have bad effects.

There is a small amount of radiation used in the X-ray scan of your body. This is what the doctor does to look at your body muscle and body fat. We do not know if this has any effect on your health. The scan does not hurt. For the test, you will lie down on a table while the scanner directs X-ray energy towards your body. This will take 15-20 minutes. Lying on the table may feel a little uncomfortable.

WILL BEING IN THE STUDY HELP ME?

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- We do not know if being in this study will help you.
- The study drug may help reduce your body weight.

WHO WILL KNOW ABOUT THIS STUDY?

The study is private. What the study doctor learns about you will be shared with your parents or legal guardian. Scientists working on the study and the part of the government that makes rules about medicine will need to see what is learned, but they are not allowed to tell anyone about you.

If any bad effects happen during the study, those effects will be reported to the United States government.

DO I HAVE TO BE IN THE STUDY?

You do not have to be in the study if you do not want to. You can stop at any time and no one will be upset with you or your parents. If you stop being in the study, this will not change the way your doctor treats you.

Tell your parents, study doctor or nurse about any parts of the study that make you feel bad. The study doctor or nurse will answer any questions you have.

I have had this study explained to me in a way that I understand, I have been given the opportunity to discuss it, and I have had the chance to ask questions. I agree to take part in this study.

Assent of Participant:

Signature of Participant

Print Name of Participant

Date**Investigator:**

Signature of Investigator

Print Name of Investigator

Date**PATIENT IDENTIFICATION****Assent to Participate in a Clinical Research Study**

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