



THE SCOUT-015 STUDY

FOR CHILDREN, ADOLESCENTS, AND
ADULTS WITH PRADER-WILLI SYNDROME



THANK YOU FOR JOINING THE SCOUT-015 STUDY.

This clinical study is being done to see if a new study drug is safe and helpful for children, adolescents, and adults who have Prader-Willi Syndrome (PWS).

This booklet will help you understand what happens at study visits. There is a glossary at the end to explain terms you may not be familiar with. Please note, when we say “you,” we mean the study participant.

There are risks and benefits to any research study. The study drug may or may not help. You could have side effects from the study drug or study tests. With your participation, other children and adults who have PWS may be helped in the future.

















The study team will happily answer any questions you may have. Remember, participation is voluntary and you can choose to leave the study at any time.

With much appreciation,
The SCOUT-015 Study Team



STUDY DURATION AND VISITS

You will be in the main study for up to 40 weeks (about 10 months). There will be about 16 study visits—10 visits will be in person at the study clinic and 6 visits will be remote by phone or video call.

Screening 3 weeks	Treatment 33 weeks			Dose Decrease and Follow-up 4 weeks
	Tolerability 6 weeks	Dose Increase 3 weeks	Maintenance 24 weeks	
1 visit 	3 visits   	3 visits   	7 visits     	2 visits  
<div> Study clinic</div> <div> Phone or video call</div>				

Come to all study visits and do your best to follow directions.

Visit 1 SCREENING



First, you will need to give your permission to join the study by signing the consent/assent forms. Then you will have health checks and tests to make sure the study is right for you.



Medicine review



Health information



Vital signs



Weight and height



Physical exam



Questionnaires



Heart test (ECG)



Blood tests



Urine test



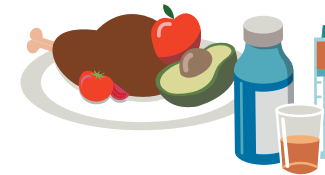
Pregnancy test (if applicable)



Side effects review

Complete all questionnaires to the best of your ability. A caregiver can do them for you. If a caregiver completes them for you, that same caregiver will need to do all remaining questionnaires throughout the study.

STUDY DRUG

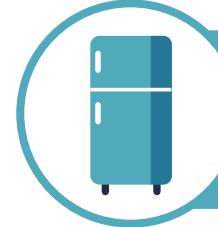


The study drug is a liquid that you take twice a day by mouth with food. It will contain the active study drug or will be placebo.

The placebo liquid contains no active medicine, but looks and tastes the same as the liquid containing the study drug. Having a placebo as part of the study is important to show which results are due to the actual treatment and are not happening by chance.



The study staff will tell you how much liquid to take. They will also give you an instruction sheet to help you properly measure the liquid at home.



Keep the study drug in the refrigerator.

Tell us if you ever have a bad reaction, miss a dose, or take too much of the study drug.



Reminder for in-person study visits: You will need to bring all empty and partially filled bottles of study drug with you every time you come to the study clinic.

Visits 2, 3, and 4 TOLERABILITY CHECK

Weeks 1 to 5

For 6 weeks, you will take the placebo to make sure you can tolerate the liquid. This will also give you time to get used to the study procedures and to taking the study drug every day.



Remember: Bring all empty and partially filled bottles of study drug with you to the study clinic.

There will be 3 clinic visits with health checks and tests.



Medicine review



Health information



Vital signs



Weight and height



Questionnaires



Side effects review



Reminder for your upcoming Visit 5: Fill out the food diary as instructed by the study team. A caregiver can do it for you. If a caregiver does complete it, that same caregiver will need to complete all remaining food diaries throughout the study.

Visit 5 FINAL ELIGIBILITY CHECK

Week 7



Remember: Do not take the study drug at home before coming to the study clinic. You will take your dose during the visit.



Remember: Bring your completed food diary to this visit.



Remember: Bring all empty and partially filled bottles of study drug with you to the study clinic.

The study doctor will do a final check to see whether you can continue the study.



Medicine review



Health information



Vital signs



Weight and height



Physical exam



Questionnaires



Heart test (ECG)



Blood tests



Urine test



Pregnancy test (if applicable)



DEXA scan (if available at your study clinic)



Side effects review

Visit 5 TREATMENT GROUP ASSIGNMENT

Week 7

If you are eligible to continue in the study, you will be randomly assigned to receive the study drug or placebo.

You are twice as likely to receive the study drug versus placebo. Neither you nor the study doctor will know which treatment group you are in.



You will start at the lowest dose level for 1 week. Then your dose may be gradually increased until you get to your assigned dose level.



You will be given the study drug and dosing supplies to use at home. Follow the instruction sheet given to you by the study team on how to take the study drug.

Visits 6 and 7 DOSE INCREASE

Weeks 8 and 9

The next 2 visits will be remote by phone or video call. Someone from the study team will check on you to see how you are doing.



Reminder for your upcoming Visit 8: Take your dose at home before coming to your appointment. Make sure you record the time you took it in your food diary. A blood sample will be taken about 4 to 8 hours after you take the dose.



Reminder for your upcoming Visit 8: Fill out the food diary as instructed by the study team. A caregiver can do it for you. If a caregiver does complete it, that same caregiver will need to complete all remaining food diaries throughout the study.

Visits 8 to 14

MAINTENANCE

Weeks 10 to 34

For the next 24 weeks you will have visits about once per month. Some will be at the study clinic and some will be remote by phone or video call.



Remember: Bring your completed food diary to Visits 8, 12, and 14.



Remember: Bring all empty and partially filled bottles of study drug with you every time you come to the study clinic.

Visit	Medicine review	Health information	Vital signs	Weight and height	Physical exam	Questionnaires	Heart test (ECG)	Blood tests	Urine test	Pregnancy test	DEXA scan (if available)	Side effects review
#8 Week 10	X	X	X	X	X	X	X	X	X	X		X
#9 Week 15	X	X										X
#10 Week 19	X	X	X	X	X	X	X	X	X	X		X
#11 Week 23	X	X										X
#12 Week 27	X	X	X	X	X	X		X	X	X		X
#13 Week 30	X	X										X
#14 Week 34	X	X	X	X	X	X	X	X	X	X	X	X

The data that the study team collects during this period will help doctors and researchers better understand the study drug's effect on hyperphagia (excessive desire for food) and its safety.

At Visit 14, you and your study doctor will decide if joining the long-term SCOUT-O16 study is right for you.

Visits 15 and 16

DOSE DECREASE AND FOLLOW-UP

Weeks 34 to 38

If you are not continuing on to the SCOUT-O16 study, you will take the study drug at home for 2 more weeks. The study team will give you a supply of decreasing doses and instructions on how to take them.

After you have stopped taking the study drug, you will have 2 final visits to check your health.

Visit	 Medicine review	 Health information	 Physical exam	 Side effects review
 #15 Week 36	X	X	X	X
 #16 Week 38	X	X		X

GLOSSARY



Blood tests: Small samples of blood will be taken using a small needle put into a vein in your arm (or another vein). Lab tests will be done on the sample to check your health. Other lab tests will also be done so the researchers can learn about what happens to the study drug in your body, such as how quickly your body gets rid of the study drug. You will have blood taken about 6 times during the study.



DEXA scan: This is a painless test that measures bone density and body composition, such as total body fat and muscle mass. You lie very still on an open, flat table (not in a tunnel or tube). A large scanning arm passes over you, sending X-rays. The technician stays in the room with you because the amount of radiation from the X-rays is very low. A doctor then examines the images on a computer.



Health information: During screening, you will be asked questions about your general health now and in the past, including surgeries or procedures you have had. Throughout the study, you will be asked about how you are feeling.



Heart test (ECG): This is a painless test called an electrocardiogram (ECG) to check the health of your heart. You will lie down and electric sensors (sticky patches) will be placed on your chest, arms, and legs. Wires from the discs carry the electrical signals from your heart to a computer so the study doctor can look at the pattern.



Medicine review: You will be asked about any medicines you are currently taking or have taken in the past.



Physical exam: The study doctor will examine your body all over. This may be done at the same time as the collection of your vital signs (blood pressure, heart rate, temperature, breathing rate, and oxygen saturation), weight, and height. At some visits the exam may be longer. At others it may be more focused on your symptoms related to PWS.



Pregnancy test: Participants who are able to get pregnant will have their urine tested for pregnancy periodically throughout the study. You will not be able to continue in the study if your pregnancy test is positive.



Questionnaires: You and/or your caregiver will complete several questionnaires during the course of the study. If you need help completing the questionnaires, the same caregiver should help you with them, from the first Screening visit until the end of the study. The questionnaires will ask about food-seeking behaviors, overall behavior, irritability, daytime sleepiness, skin picking, suicide risk, and seizure history.



Side effects review: Throughout the study, you will be monitored for any possible side effects of the study drug or tests.



Urine test: A study team member will ask you to urinate into a small cup. Your urine will be used for routine tests and screening for drugs of abuse including tetrahydrocannabinol (THC).



Vital signs: Your blood pressure, heart rate, temperature, breathing rate, and blood oxygen levels will be measured. The tests are done while you are seated after resting for a few minutes.



Weight and height: Your weight and height will be measured while you remain dressed in light clothing, without shoes.

STUDY CONTACT INFORMATION

Your Study Team:



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ISBN XXXXXXXXXXXXX

