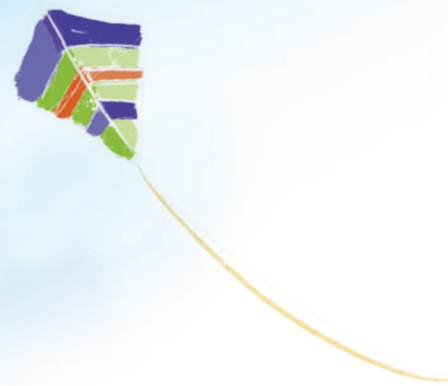


Every day, research uncovers new information about medical conditions and their treatment. Volunteer involvement in clinical studies is a key part in the development and advancement of future therapies. Results collected from clinical studies have led to thousands of medications and devices becoming available to patients all over the world.



How can I learn more about this study?

To ask questions or learn more, please contact:

Scan the QR Code to visit the study's *ClinicalTrials.gov* listing



<https://clinicaltrials.gov/ct2/show/NCT05322096>



Our goal is
to help people with
Prader-Willi syndrome
reach new heights.

Learn more about KITE-PWS, a research study testing an investigational drug that may help to control appetite.



What is a clinical study?

A clinical study (also known as a clinical trial) is designed to evaluate how safe and/or effective an experimental drug is in treating a specific disease or condition. “Experimental” describes a drug that is still being studied and has not been approved for doctors to prescribe to patients. Regulatory agencies such as the U.S. Food and Drug Administration (FDA) or the European Medicines Agency (EMA) use the results of clinical studies to decide if an experimental drug should be made available to patients.

Clinical studies are conducted by qualified medical professionals who monitor the health of participants throughout the study. Additionally, every clinical study is reviewed by an Institutional Review Board (IRB) or Ethics Committee (EC), which helps to ensure that the study is conducted safely and that the rights of study participants are protected.

Clinical studies are an important part of the journey to develop new and better treatments and improve patient care.

What is the purpose of this study?

The purpose of this study is to learn more about an experimental drug called RGH-706 in people with Prader-Willi syndrome (PWS) who have hyperphagia (abnormal increased appetite for food). About 176 people in total will take part in this study at a number of different locations around the world.

What is RGH-706?

RGH-706 is an experimental drug. It blocks a hormone called melanin-concentrating hormone (MCH). When MCH attaches to specific receptors in the brain (i.e., proteins on the outside of brain cells), it increases the desire to eat. The study will help us understand if RGH-706 is safe and effective in blocking this hormone and reducing appetite in people with PWS.

Who can be in the study?

To be in the study, participants must meet the following basic criteria:

- Are at least 17 years of age
- Have a diagnosis of PWS
- Have a body weight of greater than 40 kg (88 lbs.) and less than 200 kg (450 lbs.)
- Have had a stable body weight for the past 3 months
- Have at least 1 consistent and reliable primary caregiver who can evaluate changes in the participant’s hyperphagia symptoms, mood, health, and behavior throughout the study
- Do not have uncontrolled diabetes or diabetes that requires insulin

Medical history and other criteria will also be reviewed to determine eligibility.

What is involved in the study?

The study lasts 5-6 months and requires about 8 study visits to the study clinic. It is divided into 3 main periods. The duration of the different study periods may vary. Many of the study visits will require participants to be in a fasting state for 8 hours before the visit.

| | | |
|---|------------------------|---|
| 1 | Screening Period | Tests will be done to confirm study eligibility. |
| 2 | Study Treatment Period | If eligible, participants will be randomly assigned to study treatment with either RGH-706 or placebo (an inactive substance that looks like the experimental drug). Participants and caregivers will have 3-5 more site visits and phone calls during this period. |
| 3 | Follow-up Period | Participants and caregivers will return to the clinic 1 time during this period to check on the health of the participant. |



Why join the study?

Participants may or may not be helped from being in this clinical study. However, some benefits to consider may include:

- A chance to contribute to what we know about PWS
- A chance to help other people with PWS

Taking part in a clinical study is completely voluntary. If enrolled, participants and/or caregivers can choose to leave the study at any time and for any reason.

Will the study cost anything?

The study drug, clinic visits, and study-related procedures are provided at no cost. Participants may also receive reimbursement for time and travel. Talk to the study staff about available compensation.

