All over the world

families just like yours volunteer to participate in clinical studies to help learn more about medical conditions and their treatments. Participation in a clinical study helps doctors find new medications. The information we learn from clinical studies has led to new treatments and medications being available to billions of people around the world.

Joining a clinical study can be a way to learn more about a condition and have increased access to medical care while helping to find better treatments.

COMPASSPWS

How can I learn more about the **COMPASS PWS** study?

To ask questions or find out if your family could join the study, please contact:

Scan the QR code to visit the study website:
CompassPWS.com

ACP-101-302_Recruitment Brochure_v1.0_18Aug2023

COMPASSPWS

A new direction for people with Prader-Willi syndrome

Help us research an investigational nasal spray for hyperphagia.

What is a clinical study?

A clinical study (sometimes called a clinical trial) is research that is designed to test whether an investigational or study drug is safe and effective for the treatment of a disease or medical condition. “Investigational” means that a drug has not been approved for doctors to prescribe to patients. Regulatory authorities and health authorities use the information collected from clinical studies to help decide if an investigational drug should be made available to patients.

Before a clinical study can enroll participants, it must be reviewed and approved by an Institutional Review Board (IRB) or Ethics Committee (EC). These are groups of scientists, doctors, and members of the community who help ensure that the study is conducted safely and that the rights of participants are protected. Clinical studies are run by qualified medical professionals who monitor the health of participants during the study.

What is the purpose of the **COMPASS PWS** study?

The purpose of this study is to learn more about a study drug in participants with Prader-Willi syndrome (PWS) who have hyperphagia (excessive appetite). Around 170 families will take part at research sites all over the world.

Taking part in a clinical study is completely voluntary. Participants and caregivers can choose to leave the study at any time and for any reason.

What is the investigational drug used in the study?

The study drug being tested in this study is called carbetocin nasal spray (or ACP-101). Carbetocin nasal spray binds to oxytocin receptors with greater sensitivity than oxytocin, a naturally occurring hormone. In the study, carbetocin nasal spray or placebo is inhaled through the nose three times each day.

Who is eligible for the study?

Each participant must have a diagnosis of PWS and:

- Be 5-30 years old at the start of the study
- Have increased appetite
- Live with a caregiver who can attend study visits with the participant
- Have not used oxytocin, desmopressin (DDAVP), or tesofensine within 6 months before the start of study treatment

Other tests will be done and the participant’s medical history will be reviewed to determine eligibility.

What can I expect during the study?

The main study will last approximately 19 weeks. It will involve a maximum of 5 visits to the study center, as well as up to 2 telephone or video calls.

Screening Period (up to 3 weeks)	Tests will be completed and the participant’s medical history will be reviewed to confirm they can be in the study.
Study Treatment period (12 weeks)	Eligible participants will be randomly assigned to study treatment with either the study drug or placebo (an inactive substance) and will need to record all study treatment doses in a diary. Participants and caregivers will need to attend 5 visits to the study clinic and have 1 scheduled phone call during the study treatment period.
Open-Label Extension Study or Follow-up	After the main study, participants will be invited to enroll in COMPASS PWS OLE, a long-term, open-label extension study in which all participants will receive carbetocin nasal spray (the investigational drug) for up to 36 months. Participants who do not continue in the open-label extension study will have a follow-up phone call 30 days after the last dose of study drug.

Will the study cost anything?

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