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 Study Record



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Observational Study of VYKAT™ XR in Patients With Prader-Willi Syndrome

Enrolling by invitation

ClinicalTrials.gov ID **NCT07450664**

Sponsor **Soleno Therapeutics, Inc.**

Information provided by **Soleno Therapeutics, Inc.** (Responsible Party)

Last Update Posted **2026-05-19**

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Study Overview

Brief Summary

Prospective observational study developed to generate more evidence of the safety profile, clinical characteristics and outcomes of patients with PWS treated with VYKAT XR.

Detailed Description

Patients with PWS at participating sites who are initiating treatment or have initiated treatment with VYKAT XR, including patients who were previously treated with DCCR in a prior clinical study, will be invited to participate. Data from treatment prior to enrollment either from clinical practice or from previous DCCR clinical trials may be collected retrospectively.

Clinical care will not be mandated by the protocol.

Official Title

An Observational Study of VYKAT™ XR (Diazoxide Choline Extended-

Study Start (Actual)

2025-11-26

Primary Completion (Estimated)

2028-03

Study Completion (Estimated)

2028-03-02

Enrollment (Estimated)

200

Study Type

Observational

Soleno Therapeutics, Inc.
Exhibit 2024
Apotex v. Soleno
PGR2026-00034
 Ex. 2024-001

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participate. Data from treatment prior to enrollment either from clinical practice or from previous DCCR clinical trials may be collected retrospectively.

Clinical care will not be mandated by the protocol.

Official Title

An Observational Study of VYKAT™ XR (Diazoxide Choline Extended-Release Tablets) in Patients With Prader-Willi Syndrome (PWS)

Conditions ⓘ

Prader-Willi Syndrome

Intervention/Treatment ⓘ

- Drug: VYKAT XR

Other Study ID Numbers ⓘ

- C623

200

Study Type ⓘ

Observational

Resource links provided by the National Library of Medicine

[MedlinePlus Genetics](#) related topics: [Prader-Willi syndrome](#)

[MedlinePlus](#) related topics: [Prader-Willi Syndrome](#)

[Genetic and Rare Diseases Information Center](#) resources: [Prader-Willi syndrome](#)

[FDA Drug and Device Resources](#)

Contacts and Locations

This section provides contact details for people who can answer questions about joining this study, and information on where this study is taking place.

To learn more, please see the [Contacts and Locations section in How to Read a Study Record](#).

This study has 15 locations

United States

California Locations

Los Angeles, California, United States, 90027
Children's Hospital Los Angeles

Georgia Locations

Atlanta, Georgia, United States, 30322
Emory Children's Center

Illinois Locations

Chicago, Illinois, United States, 60611
Northwestern University Feinberg School of Medicine

Indiana Locations

Indianapolis, Indiana, United States, 46202



Ex. 2024-002

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This study has 15 locations

Emory Children's Center

Illinois Locations

Chicago, Illinois, United States, 60611
Northwestern University Feinberg School of Medicine

Indiana Locations

Indianapolis, Indiana, United States, 46202
Indiana University

Michigan Locations

Ann Arbor, Michigan, United States, 48109
University of Michigan Medical Center

Lansing, Michigan, United States, 48912
Sparrow Clinical Research Institute

Minnesota Locations

Saint Paul, Minnesota, United States, 55102
Children's Minnesota

Missouri Locations

Kansas City, Missouri, United States, 64111
Children's Mercy Hospital

New Jersey Locations

Paterson, New Jersey, United States, 07503
Saint Josephs Health

New York Locations

Valley Stream, New York, United States, 11580
Long Island Jewish Valley Stream

North Carolina Locations

Chapel Hill, North Carolina, United States, 27514
UNC Hospitals

Oregon Locations

Portland, Oregon, United States, 97227
Legacy Emanuel Medical Center

Tennessee Locations

Nashville, Tennessee, United States, 37232
Vanderbilt University Medical Center

Texas Locations

Dallas, Texas, United States, 75231
Children's Medical Center Dallas

Washington Locations

Seattle, Washington, United States, 98105
Seattle Children's Hospital



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Participation Criteria

Researchers look for people who fit a certain description, called [eligibility criteria](#). Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read [Learn About Studies](#).

Eligibility Criteria

Description

Inclusion Criteria:

- Patients currently receiving or initiating treatment with VYKAT

Ages Eligible for Study ⓘ

4 Years and older (Child, Adult, Older Adult)

Ex. 2024-003

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Eligibility Criteria

Description

Inclusion Criteria:

- Patients currently receiving or initiating treatment with VYKAT XR, including patients who previously received DCCR or are transitioning from DCCR to VYKAT XR in the context of a prior DCCR clinical trial.
- Patients and/or caregivers must provide written informed consent.

Study Population

This study will enroll patients with PWS who are currently receiving or initiating treatment with VYKAT XR.

Ages Eligible for Study ⓘ

4 Years and older (Child, Adult, Older Adult)

Sexes Eligible for Study ⓘ

All

Accepts Healthy Volunteers ⓘ

No

Sampling Method

Non-Probability Sample

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

[Expand all](#) / [Collapse all](#)

How is the study designed?

Design Details

Observational Model ⓘ : Cohort

Time Perspective: Prospective

Groups and Interventions

Groups/Cohorts ⓘ	Intervention/Treatment ⓘ
Patients with PWS who are currently receiving or initiating treatment with VYKAT XR. All patients with PWS at participating sites who are initiating treatment or have initiated treatment with VYKAT XR at the time of enrollment into this observational study, including patients who were previously treated with DCCR in a prior clinical study, will be invited to participate. Although the overall observational study is prospective, data from treatment prior to enrollment into the observational study	Drug: VYKAT XR All prospective treatment in this protocol will be commercial VYKAT XR prescribed to patients by their physicians in addition to their standard of care; patients will not receive experimental intervention or treatment from the Sponsor as part of their participation in this study.

Ex. 2024-004

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Overweight

Overnutrition

Nutrition Disorders

Nutritional and Metabolic Diseases

Prader-Willi Syndrome

Plan for Individual Participant Data (IPD)

Plan to Share Individual Participant Data (IPD)?

No

Drug and device information, study documents, and helpful links

Studies a U.S. FDA-Regulated Drug Product

Yes

Product Manufactured in and Exported from the U.S.

Yes

Studies a U.S. FDA-Regulated Device Product

No

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