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Open-Label Extension Study of DCCR in Patients With Prader-Willi Syndrome

ClinicalTrials.gov ID ⓘ NCT05701774

Sponsor ⓘ **Soleno Therapeutics, Inc.**

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

Last Update Posted ⓘ 2025-04-02

Active, not recruiting ⓘ

No longer looking for participants

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Study Details

Researcher View

No Results Posted

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Study Overview

Brief Summary

The purpose of this is study is to evaluate the long-term safety of DCCR (diazoxide choline) extended-release tablets) in patients with Prader-Willi syndrome.

Official Title

An Open-Label Study of DCCR (Diazoxide Choline) Extended-Release Tablets in Patients With Prader-Willi Syndrome

Conditions ⓘ

Prader-Willi Syndrome

Intervention/Treatment ⓘ

- Drug: DCCR

Other Study ID Numbers ⓘ

Study Start (Actual) ⓘ

2023-01-31

Primary Completion (Estimated) ⓘ

2028-06

Study Completion (Estimated) ⓘ

2028-06

Enrollment (Estimated) ⓘ

83

Study Type ⓘ

Interventional

Phase ⓘ

Phase 2

Soleno Therapeutics, Inc.
Exhibit 2023
Apotex v. Soleno
PGR2026-00034
 Ex. 2023-001

Feedback

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Prader-Willi Syndrome

Intervention/Treatment

- Drug: DCCR

Other Study ID Numbers

- C614

83

Study Type

Interventional

Phase

Phase 3

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 22 locations

United States

California Locations

- Orange, California, United States, 92868
UC Irvine
- Palo Alto, California, United States, 94304
Stanford University
- San Diego, California, United States, 92123
Rady Children's Hospital of San Diego

Florida Locations

- Gainesville, Florida, United States, 32608
U of Florida Gainesville

Georgia Locations

- Atlanta, Georgia, United States, 30329
Emory Children's Center

Indiana Locations

- Indianapolis, Indiana, United States, 46202
Indiana University School of Medicine

Maryland Locations

- Bethesda, Maryland, United States, 20892
National Institutes of Health

Massachusetts Locations

- Boston, Massachusetts, United States, 02115



Ex. 2023-002



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This study has 22 locations

indiana university school of medicine

Maryland Locations

Bethesda, Maryland, United States, 20892
National Institutes of Health

Massachusetts Locations

Boston, Massachusetts, United States, 02115
Boston Children's Hospital

Michigan Locations

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

Minnesota Locations

Saint Paul, Minnesota, United States, 55102
Children's Hospital and Clinic Minnesota

New Jersey Locations

Paterson, New Jersey, United States, 07503
St. Joseph's University Medical Center

New York Locations

Mineola, New York, United States, 11501
NYU Winthrop Hospital

Ohio Locations

Columbus, Ohio, United States, 43205
The Research Institute at Nationwide Children's Hospital

Tennessee Locations

Nashville, Tennessee, United States, 37212
Vanderbilt University

Texas Locations

Dallas, Texas, United States, 75231
Research Institute of Dallas

Utah Locations

Salt Lake City, Utah, United States, 84112
University of Utah

Washington Locations

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

United Kingdom

Cambridge, United Kingdom, CB21 5EF
Fulbourn Hospital

Glasgow, United Kingdom, G51 4TF
The Queen Elizabeth University

Hull, United Kingdom, HU3 2JZ
Hull and East Yorkshire Hospitals NHS Trust

London, United Kingdom, E1 1BB
Royal London Hospital

London, United Kingdom, SW10 9NH
Chelsea and Westminster Hospital



[Click to view interactive map](#)

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](#).

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Participation Criteria

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Eligibility Criteria	
Description	Ages Eligible for Study ⓘ
Inclusion Criteria:	4 Years and older (Child, Adult, Older Adult)
1. Provide voluntary, written informed consent (parent(s) / legal guardian(s) of patient); provide voluntary, written assent (subjects, as appropriate)	Sexes Eligible for Study ⓘ
2. Participant must:	All
1. Have participated in and completed the Study C602 Randomized Withdrawal (RW) Period;	Accepts Healthy Volunteers ⓘ
2. Have participated in but discontinued from the Study C602 RW Period and at least 16 weeks have elapsed since the date of their randomization into the C602 RW Period;	No
or	
3. Have participated in Study C602 OLE period, did not consent to participate in the RW Period, and at least 16 weeks have elapsed since the date of their C602 Open-Label Extension End of Treatment Visit.	
Exclusion Criteria:	
1. Positive urine pregnancy test (in females of child-bearing potential)	
2. Females who are pregnant or breastfeeding, and/or plan to become pregnant or to breast-feed during or within 30 days after study participation.	
3. Participation in a clinical study of an investigational drug (including approved drugs for unapproved uses), investigational device, or therapeutic intervention subsequent to the C602 Open-Label Extension End of Treatment Visit.	

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	
Primary Purpose ⓘ : Treatment	
Allocation ⓘ : N/A	

Ex. 2023-004



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[Common Questions](#)



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How is the study designed?

Design Details

Primary Purpose ⓘ : Treatment

Allocation ⓘ : N/A

Interventional Model ⓘ : Single Group Assignment

Masking ⓘ : None (Open Label)

Arms and Interventions

Participant Group/Arm ⓘ	Intervention/Treatment ⓘ
Experimental: DCCR 75 - 525 mg DCCR	Drug: DCCR <ul style="list-style-type: none">Once daily oral administration

What is the study measuring?

Primary Outcome Measures ⓘ

Outcome Measure	Measure Description	Time Frame
Safety of DCCR (adverse events. Safety analyses will be conducted in all subjects who receive at least one dose of DCCR in the C614 study. (Adverse events)	Assess the safety of DCCR by evaluating the incidence and severity of adverse events. Safety analyses will be conducted in all subjects who receive at least one dose of DCCR in the C614 study. Adverse events will be described by type and level of severity.	Baseline to End of Study or until resolution of certain adverse events

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor ⓘ

Soleno Therapeutics, Inc.

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet



How to Join a Study



Common Questions



How to Read a Study Record

Study Record Dates

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Study Registration Dates

First Submitted ⓘ

2023-01-18

First Submitted that Met QC Criteria ⓘ

2023-01-26

First Posted ⓘ

2023-01-27

Study Record Updates

Last Update Submitted that Met QC Criteria ⓘ

2025-03-28

Last Update Posted ⓘ

2025-04-02

Last Verified ⓘ

2025-03

More Information

Record History

Expand all / Collapse all

Terms related to this study

Additional Relevant MeSH Terms

- Intellectual Disability
- Neurobehavioral Manifestations
- Neurologic Manifestations
- Nervous System Diseases
- Abnormalities, Multiple
- Congenital Abnormalities
- Congenital, Hereditary, and Neonatal Diseases and Abnormalities
- Chromosome Disorders
- Genetic Diseases, Inborn
- Imprinting Disorders
- Obesity
- 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

Ex. 2023-006

Participation Criteria

Study Plan

Collaborators and Investigators

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Genetic Diseases, Imborn
Imprinting Disorders
Obesity
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

Studies a U.S. FDA-Regulated Device Product

YesNo

Product Manufactured in and Exported from the U.S.

No

Document title:	Study Details NCT05701774 Open-Label Extension Study of DCCR in Patients With Prader-Willi Syndrome ClinicalTrials.gov
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