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Open-Label Extension Study of DCCR in PWS Followed by Double-Blind, Placebo-Controlled, Randomized Withdrawal Period

ClinicalTrials.gov ID ⓘ NCT03714373

Sponsor ⓘ **Soleno Therapeutics, Inc.**

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

Last Update Posted ⓘ 2024-04-19

Completed ⓘ

No longer looking for participants

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Study Overview

Brief Summary

This is a multi-center, multi-period study with an open-label period followed by a double-blind, placebo-controlled, randomized withdrawal period evaluating the safety and efficacy of DCCR treatment.

Detailed Description

115 PWS participants who completed clinical study C601 will be enrolled into the OLE Period. All participants in the Open Label Extension (OLE) Period will receive open-label DCCR. The actual number of participants eligible to enroll in the double-blind, placebo-controlled, randomized withdrawal (RW) period will be limited to those participants taking DCCR in the OLE Period at the time of the RW Period Visit 1 (Baseline/Randomization Visit).The treatment groups in the C602 RW Period are those participants randomized to receive DCCR and those participants randomized to receive Placebo. Participants will be randomized in a 1:1 ratio (DCCR:Placebo)

Study Start (Actual) ⓘ

2018-10-01

Primary Completion (Actual) ⓘ

2023-08-17

Study Completion (Actual) ⓘ

2023-08-17

Enrollment (Actual) ⓘ

115

Study Type ⓘ

Interventional **Soleno Therapeutics, Inc. Exhibit 2021 Apotex v. Soleno PGR2026-00034 Ex. 2021-001**

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Period will receive open-label DCCR. The actual number of participants eligible to enroll in the double-blind, placebo-controlled, randomized withdrawal (RW) period will be limited to those participants taking DCCR in the OLE Period at the time of the RW Period Visit 1 (Baseline/Randomization Visit).The treatment groups in the C602 RW Period are those participants randomized to receive DCCR and those participants randomized to receive Placebo. Participants will be randomized in a 1:1 ratio (DCCR:Placebo).

Official Title

An Open-Label, Long-Term Safety and Efficacy Evaluation of Diazoxide Choline Extended-Release Tablets in Participants With Prader-Willi Syndrome With a Double-Blind, Placebo-Controlled, Randomized Withdrawal Period

Conditions

Prader-Willi Syndrome

Intervention/Treatment

- Drug: DCCR
- Drug: DCCR
- Drug: Placebo for DCCR

Other Study ID Numbers

- C602

Enrollment (Actual)

115

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.

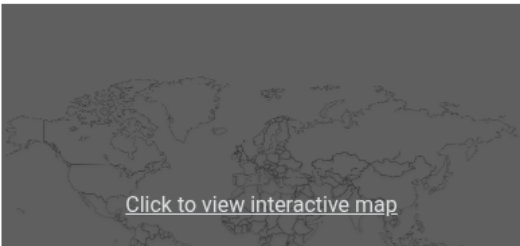
To learn more, please see the [Contacts and Locations section in How to Read a Study Record](#).

This study has 28 locations

United States

California Locations

- Orange, California, United States, 92868
University of California, Irvine
- Palo Alto, California, United States, 94305



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This study has 28 locations

United States

California Locations

-  Orange, California, United States, 92868
University of California, Irvine
-  Palo Alto, California, United States, 94305
Stanford University
-  San Diego, California, United States, 92123
Rady Children's Hospital San Diego

Colorado Locations

-  Aurora, Colorado, United States, 80045
Children's Hospital Colorado

Florida Locations

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

Georgia Locations

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

Indiana Locations

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

Kansas Locations

-  Kansas City, Kansas, United States, 66160
Kansas University Medical Center

Maryland Locations

-  Bethesda, Maryland, United States, 20892
National Institutes of Health Hatfield Clinical Research Center

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 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

-  Cleveland, Ohio, United States, 44106
University Hospitals Cleveland Medical Center
-  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, 84108



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This study has 28 locations

vanderbilt university

Texas Locations

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

Utah Locations

Salt Lake City, Utah, United States, 84108
University of Utah

Washington Locations

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



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United Kingdom

Birmingham, United Kingdom, B4 6NH
Birmingham Women's and Children's Hospital

Cambridge, United Kingdom, CB21 5ER
Fulbourn Hospital

Liverpool, United Kingdom, L9 7AL
Aintree University Hospital NHS Foundation Trust

London, United Kingdom, E1 1BB
Royal London Hospital

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

London, United Kingdom, W12 OHS
Hammersmith Hospital

Scotland Locations

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

Yorkshire Locations

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

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

OLE Period Key Inclusion Criteria:

- Successful completion of clinical study C601
- Provide voluntary, written informed consent (parent(s) / legal guardian(s) of patient); provide voluntary, written assent (subjects, as appropriate)

OLE Period Key Exclusion Criteria:

- Positive urine pregnancy test (in females of child-bearing potential) or females who are pregnant or breastfeeding, and/or plan to become pregnant or to breast-feed during or within 90 days after study participation

Ages Eligible for Study ⓘ

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

Sexes Eligible for Study ⓘ

All

Accepts Healthy Volunteers ⓘ

No

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(subjects, as appropriate)

OLE Period Key Exclusion Criteria:

- Positive urine pregnancy test (in females of child-bearing potential) or females who are pregnant or breastfeeding, and/or plan to become pregnant or to breast-feed during or within 90 days after study participation
- Any new disease, condition, or circumstance which would prevent, in the opinion of the Investigator, the patient from completing all study visits and assessments required by the protocol (e.g., an anticipated change of care setting)

RW Period Key Inclusion Criteria:

- Provide voluntary, written informed consent (parent[s] / legal guardian[s] of participant); provide voluntary, written assent (participants, as appropriate); this includes consent for randomization and potential treatment with placebo for up to 16 weeks
- Currently participating in clinical study C602 and complete the OLE End of Treatment Visit procedures

RW Period Key Exclusion Criteria:

- Positive urine pregnancy test (in females of child-bearing potential)
- Females who are pregnant or breastfeeding, and/or plan to become pregnant or to breast-feed during or within 30 days after study participation

Accepts Healthy Volunteers ⓘ

No

Study Plan

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

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How is the study designed?

Design Details

Primary Purpose ⓘ : Treatment

Allocation ⓘ : Randomized

Interventional Model ⓘ : Parallel Assignment

Masking ⓘ : Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Arms and Interventions

Participant Group/Arm ⓘ	Intervention/Treatment ⓘ
Experimental: OLE DCCR 75 - 525 mg DCCR	Drug: DCCR <ul style="list-style-type: none">Once daily oral administration of open-label DCCR tablet(s) during the OLE Period

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Participant Group/Arm ⓘ	Intervention/Treatment ⓘ
Experimental: OLE DCCR 75 - 525 mg DCCR	Drug: DCCR <ul style="list-style-type: none">Once daily oral administration of open-label DCCR tablet(s) during the OLE Period
Experimental: RW DCCR 75 - 525 mg DCCR	Drug: DCCR <ul style="list-style-type: none">Once daily oral administration of double-blind (DCCR) tablet(s) during the RW Period
Placebo Comparator: RW Placebo 75 - 525 mg Placebo for DCCR	Drug: Placebo for DCCR <ul style="list-style-type: none">Once daily oral administration of double-blind (placebo for DCCR) tablet(s) during the RW Period

What is the study measuring?

Primary Outcome Measures ⓘ

Outcome Measure	Measure Description	Time Frame
Assess the safety of DCCR by evaluating the incidence and severity of adverse events reported	Safety analyses will be conducted in all participants who receive at least one dose of DCCR. Adverse events will be described by type and level of severity.	Baseline to end of OLE (up to 4 years)
Change from RW Period Baseline in HQ-CT Total Score	Hyperphagia-related behaviors will be assessed by the hyperphagia questionnaire for clinical trials (HQ-CT), an instrument designed to measure symptoms of food related preoccupations and behaviors. The HQ-CT consists of nine items with responses ranging from 0-4 (best to worst). Scores from 9 items will be summed for a possible total score range of 0-36.	RW Period Baseline to Week 16

Secondary Outcome Measures ⓘ

Outcome Measure	Measure Description	Time Frame
Change from Baseline in HQ-CT Total Score	Hyperphagia-related behaviors will be assessed by the hyperphagia questionnaire for clinical trials (HQ-CT), an instrument designed to measure symptoms of food related preoccupations and behaviors. The HQ-CT consists of nine items with responses ranging from 0-4 (best to worst). Scores from 9 items will be summed for a possible total score range of 0-36.	Baseline to end of OLE (up to 4 years)

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Change from Baseline in HQ-CT Total Score	Hyperphagia-related behaviors will be assessed by the hyperphagia questionnaire for clinical trials (HQ-CT), an instrument designed to measure symptoms of food related preoccupations and behaviors. The HQ-CT consists of nine items with responses ranging from 0-4 (best to worst). Scores from 9 items will be summed for a possible total score range of 0-36.	Baseline to end of OLE (up to 4 years)
Change in Body Fat Mass	Change in Body Fat Mass (kg) using DXA	Baseline to end of OLE (up to 4 years)
Clinical Global Impression of Improvement (CGI-I)	CGI-I is a single statement designed to assess the Investigator's overall perception of change in the subject's condition across the course of the clinical trial. The Investigator provides a response to "Compared to the subject's condition at enrollment, the subject's condition is:" by rating the subject's behavior using a 7-point response scale (best to worst).	RW Period Week 16
Clinical Global Impression of Severity (CGI-S)	The CGI-S is a single statement designed to assess the Investigator's overall perception of the severity of the participant's illness across the course of the clinical trial. The Investigator provides a response to "Considering your total clinical experience with this particular population, how ill is this participant at this time:" by rating the subject's behavior using a 7-point response scale (best to worst).	RW Period Week 16
Assess the safety of DCCR by evaluating the incidence and severity of adverse events reported	Safety analyses will be conducted in all participants who receive at least one dose of randomized withdrawal study drug. Adverse events will be described by type and level of severity.	through the end of the RW Period, 16 weeks

Collaborators and Investigators

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

Sponsor ⓘ

Soleno Therapeutics, Inc.

Publications

From PubMed

These publications are automatically filled in from PubMed, a public database of scientific and medical articles, and may or may not be about the study.

- Strong TV, Miller JL, McCandless SE, Gevers E, Yanovski JA, Matesevac L, Bohonowych J, Ballal S, Yen K,

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Publications

From PubMed

These publications are automatically filled in from PubMed, a public database of scientific and medical articles, and may or may not be about the study.

- [Strong TV, Miller JL, McCandless SE, Gevers E, Yanovski JA, Mateševac L, Bohonowych J, Ballal S, Yen K, Hirano P, Cowen NM, Bhatnagar A. Behavioral changes in patients with Prader-Willi syndrome receiving diazoxide choline extended-release tablets compared to the PATH for PWS natural history study. J Neurodev Disord. 2024 Apr 26;16\(1\):22. doi: 10.1186/s11689-024-09536-x. ↗](#)
- [Miller JL, Gevers E, Bridges N, Yanovski JA, Salehi P, Obrynba KS, Felner EI, Bird LM, Shoemaker AH, Angulo M, Butler MG, Stevenson D, Goldstone AP, Wilding J, Lah M, Shaikh MG, Littlejohn E, Abuzzahab MJ, Fleischman A, Hirano P, Yen K, Cowen NM, Bhatnagar A; C601/C602 Investigators. Diazoxide choline extended-release tablet in people with Prader-Willi syndrome: results from long-term open-label study. Obesity \(Silver Spring\). 2024 Feb;32\(2\):252-261. doi: 10.1002/oby.23928. Epub 2023 Nov 2. ↗](#)

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 specific quality control standards before being posted on the public website.

Study Registration Dates	Study Record Updates
First Submitted ⓘ 2018-09-27	Last Update Submitted that Met QC Criteria ⓘ 2024-04-18
First Submitted that Met QC Criteria ⓘ 2018-10-19	Last Update Posted ⓘ 2024-04-19
First Posted ⓘ 2018-10-22	Last Verified ⓘ 2024-04

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Terms related to this study

Keywords Provided by Soleno Therapeutics, Inc.

PWS
Prader-Willi Syndrome

Additional Relevant MeSH Terms

Intellectual Disability
Neurobehavioral Manifestations
Neurologic Manifestations
Nervous System Diseases
Abnormalities, Multiple
Congenital Abnormalities
Congenital, Hereditary, and Neonatal Diseases and
...

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Terms related to this study	
Keywords Provided by Soleno Therapeutics, Inc.	Additional Relevant MeSH Terms
PWS	Intellectual Disability
Prader-Willi Syndrome	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

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
Yes	No

Document title: Study Details | NCT03714373 | Open-Label Extension Study of DCCR in PWS Followed by Double-Blind, Placebo-Controlled, Randomized Withdrawal Period | ClinicalTrials.gov

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Operating system: linux x64 (Node v20.18.0)

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