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A Study of Diazoxide Choline in Patients With Prader-Willi Syndrome

ClinicalTrials.gov ID
NCT03440814

Sponsor
Solenio Therapeutics, Inc.

Information provided by
Solenio Therapeutics, Inc.
(Responsible Party)

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Study Overview

Brief Summary

The purpose of this is study is to evaluate the effects of DCCR (diazoxide choline controlled release tablets) in children and adults with Prader-Willi syndrome.

Official Title

A Randomized, Double-Blind, Placebo-Controlled Study of Diazoxide Choline Controlled-Release Tablet (DCCR) in Patients With Prader-Willi Syndrome

Conditions

Prader-Willi Syndrome

Intervention/Treatment

- Drug: DCCR
- Drug: Placebo for DCCR

Study Start (Actual)

2018-05-09

Primary Completion (Actual)

2020-05-01

Study Completion (Actual)

2020-05-01

Enrollment (Actual)

127

Study Type

Interventional

Phase

Phase 2

Solenio Therapeutics, Inc.
Exhibit 2020
Apotex v. Soleno
PGR2026-00034
Ex. 2020-001

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Conditions ⓘ	Enrollment (Actual) ⓘ
Prader-Willi Syndrome	127
Intervention/Treatment ⓘ	Study Type ⓘ
- Drug: DCCR - Drug: Placebo for DCCR	Interventional
Other Study ID Numbers ⓘ	Phase ⓘ
C601	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 29 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



This study has 29 locations

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, 37232 Vanderbilt University
Texas Locations
Dallas, Texas, United States, 75231 Research Institute of Dallas
Utah Locations
Salt Lake City, Utah, United States, 84113 University of Utah
Washington Locations
Seattle, Washington, United States, 98105 Seattle Children's Hospital
United Kingdom
Birmingham, United Kingdom, B4 6NH Birmingham Women's and Children's Hospital Cambridge, United Kingdom, CB21 5ER Fulbourn Hospital Liverpool, United Kingdom, L12 2AP Alder Hey Children's Hospital NHS Foundation Trust Liverpool, United Kingdom, L9 7AL Aintree University Hospital NHS Foundation Trust London, United Kingdom, E1 1BB Royal London Hospital





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This study has 29 locations

- Liverpool, United Kingdom, L12 2AP**
Alder Hey Children's Hospital NHS Foundation Trust
- 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



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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:

- Provide voluntary, written informed consent (parent(s) / legal guardian(s) of patient); provide voluntary, written assent (patients, as appropriate)
- Genetically-confirmed Prader-Willi syndrome and hyperphagic
- In a stable care setting for at least 6 months prior to Visit 1
- Caregiver must have been caring for the patient for at least 6 months prior to Visit 1

Exclusion Criteria:

- Have participated in an interventional clinical study (i.e., investigational drug or device, approved drugs or device evaluated for unapproved use) within prior 3 months
- 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 30 days after study participation
- Any other known disease and/or condition, which would prevent, in the opinion of the Investigator, the patient from completing all study visits and assessments required by the protocol

Ages Eligible for Study

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

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

- Any other known disease and/or condition, which would prevent, in the opinion of the Investigator, the patient from completing all study visits and assessments required by the protocol

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 ⓘ : Randomized

Interventional Model ⓘ : Parallel Assignment

Masking ⓘ : Triple (Participant, Care Provider, Investigator)

Arms and Interventions

Participant Group/Arm ⓘ	Intervention/Treatment ⓘ
Experimental: DCCR 75 - 450 mg DCCR	Drug: DCCR Once daily oral administration
Placebo Comparator: Placebo 75 - 450 mg placebo for DCCR	Drug: Placebo for DCCR Once daily oral administration

What is the study measuring?

Primary Outcome Measures ⓘ

Outcome Measure	Measure Description	Time Frame
Hyperphagia Questionnaire (HQ-CT) Change From Baseline at Visit 7 (Week 13)	Hyperphagia-related behaviors were assessed by the validated hyperphagia questionnaire for clinical trials (HQ-CT), an instrument designed to measure symptoms of food related preoccupations and behaviors that was completed by the caregiver. The HQ-CT consists of nine items with responses ranging from 0-4 units each (possible total score range: 0-36). The HQ-CT was assessed at Screening, Baseline (Visit 2), and approximately every 4 weeks post-dose at Week 4, Week 8, and Week 13. A decrease in score from baseline represented improvement.	Baseline to Visit 7 (Week 13)

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CT, an instrument designed to measure symptoms of food related preoccupations and behaviors that was completed by the caregiver. The HQ-CT consists of nine items with responses ranging from 0-4 units each (possible total score range: 0-36). The HQ-CT was assessed at Screening, Baseline (Visit 2), and approximately every 4 weeks post-dose at Week 4, Week 8, and Week 13. A decrease in score from baseline represented improvement.	
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Secondary Outcome Measures ⓘ

Outcome Measure	Measure Description	Time Frame
Clinical Global Impression of Improvement (CGI-I) at Visit 7 (Week 13)	The Clinical Global Impression of Improvement (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 provided 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: Very much improved, Much improved, Minimally improved, No change, Minimally worse, Much worse, and Very much worse. The Investigator only took into account the subject's PWS condition.	at Visit 7 (Week 13)
Caregiver Global Impression of Change (GI-C) at Visit 7 (Week 13)	The Caregiver Global Impression of Change (GI-C) is a single statement designed to assess the caregiver's overall perception of change in the subject across the course of the clinical trial. The caregiver provided a response to "Please choose the response below that best describes the overall change in the person's PWS since they started taking the study medication" using a 7-point graded response scale: Very much better, Moderately better, A little better, No change, A little worse, Moderately worse, and Very much worse.	at Visit 7 (Week 13)
Change in Fat Mass (kg) From Baseline at Visit 7 (Week 13)	Whole body scans were performed. Reports included a breakdown of the following regions: left arm, right arm, trunk, left leg, right leg, and head. Each region was evaluated for body fat mass (g).	Baseline to Visit 7 (Week 13)

Collaborators and Investigators

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

Sponsor ⓘ

Soleno Therapeutics, Inc.

Investigators ⓘ

- Principal Investigator: Evelien Gevers, MD, PhD, Queen Mary University of London, Barts Health NHS Trust
- Principal Investigator: Jennifer L. Miller, MD, University of Florida

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Sponsor ⓘ

Soleno Therapeutics, Inc.

Investigators ⓘ

- Principal Investigator: Evelien Gevers, MD, PhD, Queen Mary University of London, Barts Health NHS Trust
- Principal Investigator: Jennifer L. Miller, MD, University of Florida

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, 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. ↗](#)
- [Miller JL, Gevers E, Bridges N, Yanovski JA, Salehi P, Obrynba KS, Felner EI, Bird LM, Shoemaker AH, Angulo M, Butler MG, Stevenson D, Abuzzahab J, Barrett T, Lah M, Littlejohn E, Mathew V, Cowen NM, Bhatnagar A; DESTINY PWS Investigators. Diazoxide Choline Extended-Release Tablet in People With Prader-Willi Syndrome: A Double-Blind, Placebo-Controlled Trial. J Clin Endocrinol Metab. 2023 Jun 16;108\(7\):1676-1685. doi: 10.1210/clinem/dgad014. ↗](#)

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	Results Reporting Dates	Study Record Updates
First Submitted ⓘ 2018-02-13	Results First Submitted ⓘ 2023-06-30	Last Update Submitted that Met QC Criteria ⓘ 2023-08-25
First Submitted that Met QC Criteria ⓘ 2018-02-19	Results First Posted with QC Comments ⓘ 2023-07-25	Last Update Posted ⓘ 2023-09-21
First Posted ⓘ 2018-02-22	Results First Submitted that Met QC Criteria ⓘ 2023-08-25	Last Verified ⓘ 2023-06
	Results First Posted ⓘ 2023-09-21	

Studies a U.S. FDA-Regulated Drug Product

Yes

Studies a U.S. FDA-Regulated Device Product

No

Study Documents ⓘ Provided by **Soleno Therapeutics, Inc.**

- [Study Protocol and Statistical Analysis Plan](#) [PDF, 1.17MB, 2019-06-11]

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