



The U.S. government does not review or approve the safety and science of all studies listed on this website.

Read our full [disclaimer](#) for details.

An Open-Label Study of Diazoxide Choline in Patients With Genetic Obesities

ClinicalTrials.gov ID ⓘ NCT05532020

Sponsor ⓘ Soleno Therapeutics, Inc.

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

Last Update Posted ⓘ 2022-09-08

Unknown status ⓘ

Last Verified ⓘ

2022-09 by Soleno Therapeutics, Inc.

Last Known Status Was

Not yet recruiting

Download

Save

+ Expand all content

– Collapse all content

Study Details

Researcher View

No Results Posted

Record History

On this page

Study Overview

Contacts and Locations

Participation Criteria

Study Plan

Collaborators and Investigators

Study Record Dates

More Information



How to Join a Study



Common Questions

Study Overview

Brief Summary

This is a phase 2 open-label, one-arm, clinical study to evaluate the efficacy and safety of DCCR (diazoxide choline) extended-release tablets over 1 year of treatment, in patients with genetic obesities.

Detailed Description

Patients aged 5 years and older with obesity due to SH2B1 deficiency obesity, obesity associated with PCSK1 mutation (rs6232 variant), or SIM1 deficiency obesity will be enrolled into this phase 2 open-label clinical trial at a single clinical center in North America. All eligible participants will receive DCCR (diazoxide choline) extended-release tablets for 1 year.

Official Title

An Open-Label Study to Assess the Preliminary Efficacy and Safety of DCCR (Diazoxide Choline) Extended-Release Tablets in Patients With Genetic Obesities

Study Start (Estimated) ⓘ

2023-01

Primary Completion (Estimated) ⓘ

2024-01

Study Completion (Estimated) ⓘ

2024-03

Enrollment (Estimated) ⓘ

30

Study Type ⓘ

Interventional

Phase ⓘ

Phase 2

Soleno Therapeutics, Inc.
Exhibit 2019
Apotex v. Soleno
PGR2026-00034
Ex. 2019-001

Feedback

On this page

Study Overview

Contacts and Locations

Participation Criteria

Study Plan

Collaborators and Investigators

Study Record Dates

More Information

[How to Join a Study](#)

[Common Questions](#)

[How to Read a Study Record](#)

at a single clinical center in North America. All eligible participants will receive DCCR (diazoxide choline) extended-release tablets for 1 year.

Official Title

An Open-Label Study to Assess the Preliminary Efficacy and Safety of DCCR (Diazoxide Choline) Extended-Release Tablets in Patients With Genetic Obesity

Conditions

- SH2B1 Deficiency Obesity
- Obesity Associated With PCSK1 Mutation (rs6232 Variant)
- SIM1 Deficiency Obesity

Intervention/Treatment

- Drug: DCCR (diazoxide choline) extended-release tablets

Other Study ID Numbers

- C615

Resource links provided by the National Library of Medicine

[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](#).

Study Contact

Name: Project Manager
Phone Number: 650-353-2051
Email: C615ProjectManager@soleno.life

No location data

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

Enrollment (estimated)	30
Study Type	Interventional
Phase	Phase 2



[How to Join a Study](#)



[Common Questions](#)



[How to Read a Study Record](#)

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

Key Inclusion Criteria:

- Provide voluntary, written informed consent (parent(s) / legal guardian(s) of patient); provide voluntary, written assent (patients, as appropriate)
- Genetically-confirmed diagnosis of SH2B1 deficiency obesity, obesity associated with PCSK1 mutation (rs6232 variant), or SIM1 deficiency obesity

Key Exclusion Criteria:

- Have participated in an interventional clinical study (i.e., investigational drug or device, approved drugs or device evaluated for unapproved use) within 60 days prior to Screening
- Any 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
- 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

Ages Eligible for Study ⓘ

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

Sexes Eligible for Study ⓘ

All

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.

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

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: Open-label DCCR 75 - 525 mg DCCR	Drug: DCCR (diazoxide choline) extended-release tablets All participants will be titrated over a four week period to the

Ex. 2019-003



[How to Join a Study](#)



[Common Questions](#)



[How to Read a Study Record](#)

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

Study Registration Dates

First Submitted ⓘ

2022-09-04

First Submitted that Met QC Criteria ⓘ

2022-09-07

First Posted ⓘ

2022-09-08

Study Record Updates

Last Update Submitted that Met QC Criteria ⓘ

2022-09-07

Last Update Posted ⓘ

2022-09-08

Last Verified ⓘ

2022-09

More Information

Record History

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

Terms related to this study

Keywords Provided by **Soleno Therapeutics, Inc.**

SH2B1 deficiency obesity
Obesity associated with PCSK1 mutation
(rs6232 variant)
SIM1 deficiency obesity
Genetic obesity

Plan for Individual Participant Data (IPD)

Plan to Share Individual Participant Data (IPD)?

No

Drug and device information, study documents, and helpful links

Ex. 2019-005



How to Join a Study



Common Questions



How to Read a Study Record

Obesity associated with PCSK1 mutation (rs6232 variant)
SIM1 deficiency obesity
Genetic obesity

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

Studies a U.S. FDA-Regulated Device Product

No

Product Manufactured in and Exported from the U.S.

No

About

[About ClinicalTrials.gov](#)

[Release Notes](#)

[Site Map](#)

Help

[Give us feedback](#)

[Glossary](#)

[Customer Support](#)

Legal

[Disclaimer](#)

[Terms and Conditions](#)

Clinical Trials.gov

National Library of Medicine
8600 Rockville Pike, Bethesda, MD
20894



National Library of Medicine
National Center for Biotechnology Information

[ClinicalTrials.gov](#)

An official website of the [U.S. Department of Health and Human Services](#), [National Institutes of Health](#), [National Library of Medicine](#), and [National Center for Biotechnology Information](#).

Document title: Study Details | NCT05532020 | An Open-Label Study of Diazoxide Choline in Patients With Genetic Obesity | ClinicalTrials.gov

Capture URL: <https://clinicaltrials.gov/study/NCT05532020?spons=Soleno%20Therapeutics,%20Inc.&viewType=Card&rank=3>

Captured site IP: 194.39.69.141

Page loaded at (UTC): Thu, 11 Jun 2026 16:28:16 GMT

Capture timestamp (UTC): Thu, 11 Jun 2026 16:28:18 GMT

Capture tool: 3.20.10

Collection server IP: 52.87.188.130

Browser engine: Mozilla/5.0 (X11; Linux x86_64) AppleWebKit/537.36 (KHTML, like Gecko) Chrome/149.0.0.0 Safari/537.36

Operating system: linux x64 (Node v20.18.0)

Capture ID: 3NG1FBu5tjmoqDmtEH6BtQ