

Record 11 of 48



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Read our full [disclaimer](https://clinicaltrials.gov/about-site/disclaimer) (<https://clinicaltrials.gov/about-site/disclaimer>) for details.

Terminated ⓘ

Study SPR001-203 did not meet its primary and secondary endpoints therefore Spruce Biosciences has decided to terminate the study

A Ph2b to Evaluate Clinical Efficacy and Safety of Tildacerfont in Adult CAH

ClinicalTrials.gov ID ⓘ NCT04457336

Sponsor ⓘ **Spruce** Biosciences

Information provided by ⓘ **Spruce** Biosciences (Responsible Party)

Last Update Posted ⓘ 2024-06-10

Study Details Tab

Study Overview

Brief Summary

An investigation of the efficacy and safety of up to 70 weeks of treatment with Tildacerfont in subjects with classic CAH who have elevated biomarkers at baseline on their current GC regimen. Optional open label treatment extension period up to 240 weeks with 200mg Tildacerfont QD.

Detailed Description

This is a study that will test the efficacy and safety of Tildacerfont. The first 12-weeks will be a double-blind, placebo controlled, dose ranging study. The following 58-weeks will assess the long term safety of Tildacerfont. Optional open label treatment extension period up to 240 weeks with 200mg Tildacerfont QD.

Official Title

A Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging Study to Evaluate the Efficacy and Safety of SPR001 (Tildacerfont) in Adult Subjects With Classic Congenital Adrenal Hyperplasia Conditions ⓘ

Congenital Adrenal Hyperplasia

Intervention / Treatment ⓘ

- Drug: Tildacerfont/Placebo

Other Study ID Numbers ⓘ

- CAHmelia 203 (Other Identifier) (OTHER: Spruce Biosciences)

Study Start (Actual) ⓘ

2020-08-26

Primary Completion (Actual) ⓘ

2024-02-09

Study Completion (Actual) ⓘ

2024-05-23

Enrollment (Actual) ⓘ

96

Study Type ⓘ

Interventional

Phase ⓘ

Phase 2

Resource links provided by the National Library of Medicine

MedlinePlus Genetics (<https://medlineplus.gov/genetics/>) related topics: 21-hydroxylase deficiency. (<https://medlineplus.gov/genetics/condition/21-hydroxylase-deficiency>).

Genetic and Rare Diseases Information Center (<https://rarediseases.info.nih.gov/gard>) resources: 21-hydroxylase Deficiency. (<https://rarediseases.info.nih.gov/diseases/5757/21-hydroxylase-deficiency>). Congenital Adrenal Hyperplasia (<https://rarediseases.info.nih.gov/diseases/1467/congenital-adrenal-hyperplasia>). Hyperadrenalism (<https://rarediseases.info.nih.gov/diseases/8252/hyperadrenalism>).

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](https://clinicaltrials.gov/study-basics/how-to-read-study-record#contacts-and-locations) section in [How to Read a Study Record](https://clinicaltrials.gov/study-basics/how-to-read-study-record#contacts-and-locations) (<https://clinicaltrials.gov/study-basics/how-to-read-study-record#contacts-and-locations>).

This study has 65 locations

United States

Alabama Locations

 **Birmingham, Alabama, United States, 35294**
Spruce Study Site

California Locations

 **Los Angeles, California, United States, 90027**
Spruce Study Site

 **Orange, California, United States, 92868**
Spruce Clinical Site

 **Sacramento, California, United States, 95817**
Spruce Study Site

Colorado Locations

 **Englewood, Colorado, United States, 80113**
Spruce Study Site

Florida Locations

 **Tampa, Florida, United States, 33612**
Spruce Clinical Site

 **West Palm Beach, Florida, United States, 33401**
Spruce Study Site

Illinois Locations

 **Chicago, Illinois, United States, 60611**
Spruce Study Site

Indiana Locations

-  Indianapolis, Indiana, United States, 46202
Spruce Clinical Site

Maryland Locations

-  Baltimore, Maryland, United States, 21287
Spruce Study Site

Minnesota Locations

-  Minneapolis, Minnesota, United States, 55454
Spruce Clinical Site
-  Rochester, Minnesota, United States, 55905
Spruce Study Site

Nevada Locations

-  Las Vegas, Nevada, United States, 89148
Spruce Clinical Site

North Carolina Locations

-  Hickory, North Carolina, United States, 28601
Spruce Study Site

Ohio Locations

-  Canton, Ohio, United States, 44718
Spruce Study Site
-  Cincinnati, Ohio, United States, 45219
Spruce Study Site
-  Cleveland, Ohio, United States, 44195
Spruce Study Site
-  Columbus, Ohio, United States, 43210
Spruce Study Site

Oregon Locations

-  Bend, Oregon, United States, 97702
Spruce Clinical Site

Pennsylvania Locations

-  Philadelphia, Pennsylvania, United States, 19104
Spruce Study Site
-  Philadelphia, Pennsylvania, United States, 19107
Spruce Study Site

Rhode Island Locations

-  Providence, Rhode Island, United States, 02903
Spruce Study Site

South Carolina Locations

-  Columbia, South Carolina, United States, 28203
Spruce Study Site

Tennessee Locations

-  Memphis, Tennessee, United States, 38163
Spruce Clinical Site

Texas Locations

-  Austin, Texas, United States, 78731
Spruce Study Site
-  Dallas, Texas, United States, 75093
Spruce Study Site
-  Edinburg, Texas, United States, 78539
Spruce Clinical Site
-  Fort Worth, Texas, United States, 76104
Spruce Clinical Site

Australia

-  Brisbane, Australia
Spruce study site
-  Elizabeth Vale, Australia
Spruce Study Site
-  Melbourne, Australia
Spruce Study Site

Western Australia Locations

-  Nedlands, Western Australia, Australia, 6009
Spruce Study Site

Brazil

-  Brasília, Brazil
Spruce Study Site
-  São Paulo, Brazil
Spruce Study Site

Canada

-  Ottawa, Canada, K1H7W9

Spruce Study Site

 **Sherbrooke, Canada, J1H 5N4**
Spruce Study Site

Newfoundland and Labrador Locations

 **St. John's, Newfoundland and Labrador, Canada**
Spruce Study Site

Ontario Locations

 **London, Ontario, Canada**
Spruce Study Site

Denmark

 **Aarhus, Denmark**
Spruce Study Site

 **Copenhagen, Denmark**
Spruce Study Site

Estonia

 **Tallinn, Estonia**
Spruce Study Site

 **Tartu, Estonia**
Spruce Study Site

Germany

 **Munich, Germany**
Spruce Study Site

Ireland

 **Dublin, Ireland**
Spruce Study Site

Italy

 **Milan, Italy**
Spruce Study Site

 **Napoli, Italy**
Spruce Study Site

 **Rome, Italy**
Spruce Study Site

 **Torino, Italy**
Spruce Study Site

Korea, Republic of

 **Seoul, Korea, Republic of**

Latvia

-  **Riga, Latvia**
Spruce Study Site

Lithuania

-  **Kaunas, Lithuania**
Spruce Study Site

Netherlands

-  **Nijmegen, Netherlands**
Spruce Study Site

Poland

-  **Kraków, Poland**
Spruce Study Site
-  **Warsaw, Poland**
Spruce Study Site

Romania

-  **Bucharest, Romania**
Spruce Study Site

Spain

-  **Barcelona, Spain**
Spruce Study Site
-  **Madrid, Spain**
Spruce Study Site
-  **Sevilla, Spain**
Spruce Study Site
-  **Tarragona, Spain**
Spruce Study Site

Sweden

-  **Falun, Sweden**
Spruce Study Site
-  **Stockholm, Sweden**
Spruce Study Site

Switzerland

-  **Saint Gallen, Switzerland**
Spruce Study Site
-  **Zürich, Switzerland**

Turkey

 **Istanbul, Turkey**
Spruce Study Site

United Kingdom

 **Birmingham, United Kingdom**
Spruce Study Site

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](https://clinicaltrials.gov/study-basics/learn-about-studies) (<https://clinicaltrials.gov/study-basics/learn-about-studies>).

Eligibility Criteria

Description

Inclusion Criteria:

- Male and female subjects over 18 years old, inclusive
- Has a known childhood diagnosis of classic CAH due to 21-hydroxylase deficiency based on genetic mutation in CYP21A2 and/or documented elevated 17-OHP and currently treated with HC, HC acetate, prednisone, prednisolone, methylprednisolone (or a combination of the aforementioned GCs)
- Has been on a stable supraphysiologic dose of GC replacement ≥ 15 mg/day and ≤ 60 mg/day in HC equivalents
- For subjects with the salt-wasting form of CAH, subject has been on a stable dose of mineralocorticoid replacement for ≥ 1 month before screening

Exclusion Criteria:

- Has a known or suspected diagnosis of any other known form of classic CAH (not due to 21 hydroxylase deficiency)
- Has a history that includes bilateral adrenalectomy or hypopituitarism
- Has a history of allergy or hypersensitivity to Tildacerfont, any of its excipients, or any other CRF1 receptor antagonist
- Current treatment with dexamethasone as GC therapy for CAH. Prior treatment with dexamethasone is allowed as long as the transition to an alternative GC regimen (eg, HC, prednisone, or prednisolone) has resulted in a stable dose of GC replacement for ≥ 1 month before screening.
- Shows clinical signs or symptoms of adrenal insufficiency

Ages Eligible for Study ⓘ

18 Years and older (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.

How is the study designed?

Design Details

Primary Purpose ⓘ : Treatment

Allocation ⓘ : Randomized

Interventional Model ⓘ : Parallel Assignment

Interventional Model Description: Subjects will be randomized in a 1:1:1:1 manner to one of three doses of Tildacerfont or Placebo.

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

Masking Description: Double-Blind

Participant Group/Arm ❶	Intervention/Treatment ❶
Experimental: Tildacerfont Group 1 Tildacerfont administered daily via oral tablet for 12 weeks at dose level 1	Drug: Tildacerfont/Placebo • Tablet, administered daily • Other Names: ◦ SPR001
Experimental: Tildacerfont Group 2 Tildacerfont administered daily via oral tablet for 12 weeks at dose level 2	Drug: Tildacerfont/Placebo • Tablet, administered daily • Other Names: ◦ SPR001
Experimental: Tildacerfont Group 3 Tildacerfont administered daily via oral tablet for 70 weeks at dose level 3	Drug: Tildacerfont/Placebo • Tablet, administered daily • Other Names: ◦ SPR001
Placebo Comparator: Placebo Placebo administered daily via oral tablet for 12 weeks.	Drug: Tildacerfont/Placebo • Tablet, administered daily • Other Names: ◦ SPR001

What is the study measuring?

Primary Outcome Measures ❶

Outcome Measure	Measure Description	Time Frame
Change in androstenedione	Percent change of androstenedione	12 weeks

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Proportion of subjects who achieve reduction A4 levels	Proportion of subjects who achieve $A4 \leq \text{ULN}$	12 weeks
Proportion of subjects who achieve reduction in 17-OHP	Proportion of subjects who achieve $17\text{-OHP} \leq 1200\text{ng/dL}$	12 weeks
Effectiveness in reducing TART(s) in Male CAH subjects	Change in lesion volume of TART(s) from baseline	12 weeks

Collaborators and Investigators

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

Sponsor

Spruce Biosciences

Investigators ⓘ

- Principal Investigator: Kyriakie Sarafoglou, M.D, Dept. of Pediatrics, Divisions of Endocrinology and Genetics & Metabolism, Univ. of Minnesota

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 ⓘ	2020-06-25
First Submitted that Met QC Criteria ⓘ	2020-06-30
First Posted ⓘ	2020-07-07

Study Record Updates	
Last Update Submitted that met QC Criteria ⓘ	2024-06-06
Last Update Posted ⓘ	2024-06-10
Last Verified ⓘ	2024-06

More Information

Terms related to this study	
Keywords Provided by Spruce Biosciences	
CAH	
Adrenal Disorder	

Congenital Adrenal Hyperplasia

Additional Relevant MeSH Terms

Pathologic Processes
Disorders of Sex Development
Urogenital Abnormalities
Female Urogenital Diseases
Female Urogenital Diseases and Pregnancy Complications
Urogenital Diseases
Male Urogenital Diseases
Congenital Abnormalities
Genetic Diseases, Inborn
Steroid Metabolism, Inborn Errors
Metabolism, Inborn Errors
Metabolic Diseases
Adrenal Gland Diseases
Endocrine System Diseases
Gonadal Disorders
Adrenal Hyperplasia, Congenital
Adrenogenital Syndrome
Adrenocortical Hyperfunction
Hyperplasia

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