CAHmelia
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EXPLORE THE POSSIBILITY OF CHANGING YOUR CLASSIC CAH JOURNEY

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Living with Classic Congenital Adrenal Hyperplasia (CAH)

Classic Congenital Adrenal Hyperplasia (CAH) is a rare genetic condition that affects the body's ability to create and regulate key hormones. Most significantly, CAH alters the production of cortisol, which is known as the "stress hormone." CAH also affects the production of aldosterone, which regulates salt and water balance in your body, and androgens which are testosterone-related hormones present in men and women.[1]

Your body may be sending you a message about hormone imbalance from glucocorticoid (steroid) under-treatment or over-treatment.[1]

Glucocorticoid related signs and symptoms to W.A.T.C.H.

- Weight Gain
- Appetite Increase
- Temperament/Mood Changes
- Circular or Moon Face
- Hair Growth & Acne (facial)

Managing CAH

Do you live with classic Congenital Adrenal Hyperplasia (CAH)?

Currently, glucocorticoid (GC) therapy is the only approved treatment for classic CAH. GCs are a type of steroid treatment that can help you manage your condition by replacing deficient cortisol and reducing androgen levels.[2]

Replacing cortisol with steroids is necessary to maintain health in people with CAH. However, many people with classic CAH also need steroids to decrease their androgen production to control symptoms such as excess body hair, fertility challenges, irregular menstrual periods, and testicular adrenal rest tumors (TARTS).[2]

Steroid therapy goals are to prevent life-threatening adrenal crisis across all ages, provide balanced hormone levels and promote normal growth and development.

A survey of 113 CAH participants stated that they do not feel sufficiently informed about their treatment:

of participants felt they did not have enough access to information to make an informed choice about GC treatment

of participants are willing to change their current regimen if they could lower their dose of steroid

Data on file Spruce Biosciences participant survey 2022

What is the CAHmelia Study?

Before a medication can be prescribed by a health care provider, it must be tested. Clinical trial programs are health-related research studies in humans that follow a pre-defined, detailed plan to determine the safety and effectiveness of the investigational medication for its intended use.

The primary purpose of the CAHmelia program is to assess if tildacerfont is effective in lowering androgens (testosterone-related hormones) and daily glucocorticoid doses in adults with classic CAH. The CAHmelia studies are dedicated to exploring solutions for people living with classic CAH.[4,5]

What is tildacerfont?

Tildacerfont is a new type of oral, once-daily investigational drug that is NOT a steroid.[3] By reducing the amount of androgens (testosterone-related hormones) your body makes, tildacerfont may improve your classic CAH symptoms.[3] This investigational drug will not replace your steroid treatment but may allow you to manage your condition with lower amounts of steroids.

Is tildacerfont safe?

Tildacerfont is generally well-tolerated in healthy volunteers and in people with classic CAH:

- Generally well-tolerated at doses under evaluation
- Generally well-tolerated across a diverse group of people

Who can take part in this Study?

You may be able to take part if you*:

- Are at least 18 years of age
- Have a confirmed diagnosis of classic CAH due to 21-OH deficiency
- Take steroids daily (glucocorticoids with or without mineralocorticoids)
- Taking part is completely voluntary, and you may choose to stop at any time.

*Other criteria applies

What can I expect if I enroll?

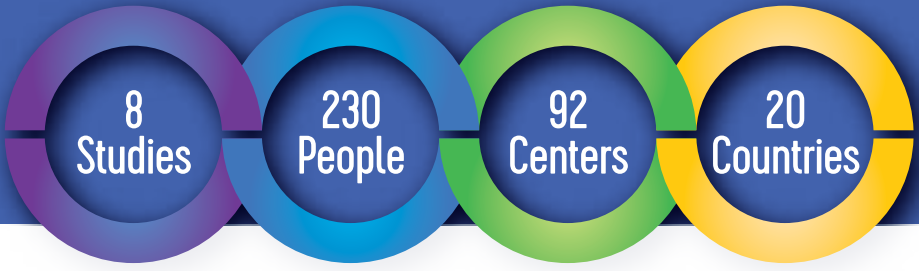
Before the Study

Evaluations will be done (either at the clinic and/or at home) to see if you can take part in the trial.

During the Study

You will be chosen at random to receive either tildacerfont or a placebo (inactive pill). After the placebo period, everyone will receive tildacerfont. Visits and laboratory tests (blood and/or urine) will be done regularly during the study to monitor the safety of your treatment. Flexible visit schedules may allow evaluations in clinic or at home.

Tildacerfont is generally well-tolerated in healthy volunteers and people with classic CAH. Tildacerfont global history includes:



FAQ's

Who qualifies for the CAHmelia Studies?

18 years of age and older and diagnosed with classic congenital adrenal hyperplasia.

Can I participate if I have non-classic CAH?

At this time, only individuals with classic CAH (including salt-wasting and simple virilizing) due to 21-hydroxylase deficiency are eligible for the CAHmelia studies.

Who is conducting the CAHmelia studies?

The CAHmelia studies are sponsored by Spruce Biosciences across 20 different countries, including the United States, Canada, Europe, South America, Asia and Australia.

Where will my study visits take place?

In certain circumstances, you can choose to have home health-care visits or telemedicine appointments instead of visits that would normally be in the clinic. For some tests, you will need to visit the clinic.

Will participants stop taking steroid treatment when starting tildacerfont?

Participants will NOT stop taking steroid treatment. Tildacerfont will not replace your steroid treatment but may allow you to manage your condition with lower doses of steroids.

What if I want to stop participating in the CAHmelia study?

Participation in CAHmelia studies are completely voluntary, you can freely withdraw (discontinue participation) at any time during the clinical trial.

What does it cost?

CAHmelia participants will receive CAHmelia study-related care, including medical tests, clinical care, stress-dosing steroids, and tildacerfont at no cost.

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Healthcare provider's information

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More information on the CAHmelia studies can be found at: *www.CAHstudy.com*
or email: *CAHmelia@sprucebiosciences.com*

References:

1. Claahsen-van der Grinten HL, et al. Endocr Rev. 2022;43(1):91-159.doi: 10.1210/endrev/bnab016; 2. Speiser PW, et al. J Clin Endocrinol Metab. 2018;103:4043–88; 3.Sarafoglou K, et al. J Clin Endocrinol Metab. 2021;106(11):e4666-e4679. doi:10.1210/clinem/dgab438; 4. ClinicalTrials.gov. NCT04544410. Available at: https://clinicaltrials.gov/ct2/show/NCT04544410 (accessed May 23, 2022); 5. ClinicalTrials.gov.NCT04457336. Available at: https://clinicaltrials.gov/ct2/show/NCT04457336 (accessed May 23, 2022).