

IS CLINICAL RESEARCH RIGHT FOR ME?

Volunteer participation in clinical research is a personal decision and can only be made by you.

HELPING OTHERS LIVING WITH CLASSIC CAH

By taking part in a clinical trial, you're contributing to science and helping to advance research that may improve quality of life for many people including yourself.

WHAT ARE THE CAHmelia CLINICAL TRIALS?

ABOUT CAHmelia 203

A Randomized, Double-Blind, Placebo-Controlled* Dose-Ranging Study to Evaluate the Efficacy and Safety of Tildacerfont in Adult Subjects with Classic Congenital Adrenal Hyperplasia

OBJECTIVE

To evaluate the ability of tildacerfont to reduce abnormal androgens and improve clinical outcomes over 52 weeks

POPULATION

Adults with classic CAH with abnormal androgens and a wide range of daily steroid dose

ABOUT CAHmelia 204

A Randomized, Double-Blind, Placebo-Controlled* Study to Evaluate the Efficacy and Safety of Tildacerfont in Reducing Supraphysiologic Glucocorticoid Use in Adult Subjects with Classic Congenital Adrenal Hyperplasia

OBJECTIVE

To evaluate the ability of tildacerfont to reduce daily steroid dose and reduce adverse outcomes associated with high steroid doses over 52 weeks

POPULATION

Adults with classic CAH and high levels of daily steroid dose

* All subjects will be eligible to receive at least 6 months of tildacerfont treatment in either study
Tildacerfont is an investigational drug that is not FDA-approved

WHAT SHOULD I EXPECT IF I PARTICIPATE IN A CAHmelia TRIAL?

Before joining a CAHmelia trial, you will be screened to check if the study is right for you. If eligible, you will:

- Begin taking study medication alongside your steroid regimen
- Keep an electronic diary to capture relevant daily information
- Receive a high standard of care with dedicated and experienced clinical staff, who will evaluate your health and progress
- All study-related care, including medical tests, clinical care, and the investigational study drug, will be provided at no cost to you
- Due to the impact of COVID-19, study visits are a combination of at-home visits, telemedicine visits and limited in-person visits

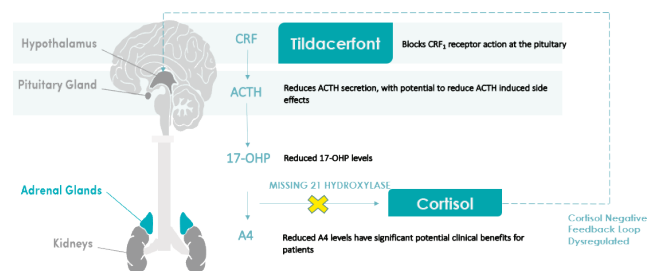


WHAT IS TILDACERFONT?

Tildacerfont is a new oral, non-steroidal investigational medicine that is being studied for the treatment of classic CAH by blocking certain hormone receptors on the molecular level, thereby potentially decreasing patient reliance on steroids. If trials are successful, it could become the first approved daily treatment developed specifically for patients with classic CAH.

HOW DOES TILDACERFONT WORK?

Tildacerfont works by blocking the CRF1 receptor and thereby preventing ACTH overproduction and consequent androgen buildup.



IS TILDACERFONT SAFE?

Tildacerfont is generally well tolerated in healthy volunteers and in patients with classic CAH.

- No reported drug-related serious adverse events (SAEs)
- Generally well tolerated at effective doses
- Generally well tolerated across a diverse array of patients (old and young, male and female, better controlled, poorly controlled, normal and obese)

HOW WILL TILDACERFONT AFFECT HOW I LOOK/FEEL?

Tildacerfont works to counteract classic CAH's effects on androgen production and may affect certain traits like body hair, weight, growth and acne.

During your initial clinic visit, you'll have a chance to talk with doctors at length about how tildacerfont might affect your body.

The studies will also assess how tildacerfont affects cholesterol, blood pressure, bone mineral density (BMD) and in males, testicular adrenal rest tumors (TARTS).

WHAT HAPPENS DURING THE TREATMENT PHASE?

Participants in CAHmelia 203 or 204 will be randomized to either placebo or tildacerfont for 12 or 24 weeks, respectively.

All participants will have the opportunity to receive tildacerfont for at least 6 months.

All participants will have periodic study visits during the treatment phase.

During these visits, participants will meet with the study team, answer questionnaires, and have their blood drawn for testing.

WILL YOU BE ABLE TO STOP TAKING STEROID TREATMENTS IN THE CAHMELIA STUDIES?

Study participants will continue to receive steroids for the duration of the trial.

While tildacerfont ultimately seeks to significantly reduce steroid use, tildacerfont will not be a complete replacement for steroids.

ARE THERE ANY OVERNIGHT HOSPITAL VISITS IN THE CAHMELIA TRIALS?

There are no overnight visits in either study.

Study visits are conducted using a combination of an at-home visit and either telemedicine or in-person visits.

DO I HAVE TO GO TO THE HOSPITAL FOR BLOOD DRAWS?

Participants in CAHmelia 203 or 204 will have periodic blood draws to assess how you are doing on either the placebo or tildacerfont.

Due to the impact of COVID-19, study visits may be a combination of at-home visits and limited in-person visits.

HOW LONG WILL THE STUDY LAST?

- The study you are eligible to take part in may last ~1 year with several clinic visits within this time
- During these visits, you will meet with the study team, answer questionnaires, and have your blood drawn for testing
- Due to the impact of COVID-19, study visits are a combination of at-home visits, telemedicine visits and limited in-person visits
- Participation is completely voluntary, and you may choose to discontinue at any time

WHAT DOES IT COST TO PARTICIPATE IN A CAHMELIA STUDY?

- If you are selected to participate, you will receive all study-related care, including medical tests, clinical care, and tildacerfont tablets at no cost
- If the study site necessitates travel due to location, Clara Health will make travel arrangements and travel support with no out-of-pocket expenses incurred by you
- Travel support may also include meal expense reimbursement on study visit days.
- You may be reimbursed a small amount for daily completion of your electronic diary confirming you took the study medication depending on the clinical trial site approval

CAN I PARTICIPATE IF I HAVE NON-CLASSIC CAH?

At this time, only individuals with a documented diagnosis of classic CAH due to 21-hydroxylase deficiency are eligible for the tildacerfont trial.

If it's determined that this study is not a good fit for you, the team at Clara Health at hello@clarahealth.com or (415) 326-8831 can help you explore other clinical trial options.

WHAT DO I DO NEXT IF I AM INTERESTED IN LEARNING MORE?

Go to CAHstudy.com or call ClaraHealth at **415-326-8831**

