



Are you caring for  
someone who has

**CDKL5  
deficiency  
disorder?**



Find out more about the GEMZ Study and how to join







If your child or someone you care for is being treated for epileptic seizures associated with CDKL5 deficiency disorder (CDD), please consider the GEMZ Study.

The study is testing an investigational medication taken by mouth (orally) in participants aged 2 to 35 years old who are living with CDD. Please talk to a study team member to learn more.

## About the GEMZ Study

The GEMZ Study is testing an oral medication called ZX008 (fenfluramine hydrochloride) in participants who have frequent epileptic seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD).

## Who can join the GEMZ Study?

In order to participate in the GEMZ Study, patients must:

- Be between 2 and 35 years of age
- Have a confirmed mutation in the CDKL5 gene which is thought to be causing their disease
- Have a diagnosis of CDD with epilepsy first starting in the first year of life
- Have motor and developmental delays
- Have uncontrolled seizures despite previous or current use of 2 or more antiseizure treatments
- Currently be receiving at least 1 antiseizure treatment
- Currently not be receiving more than 4 antiseizure medications (excluding rescue medications)
- Have 4 or more motor seizures per week
- Have not previously been treated with Fintepla® (fenfluramine hydrochloride)

There are additional criteria that need to be met. The study team will go into more detail with you and clarify any questions you have about the above requirements.

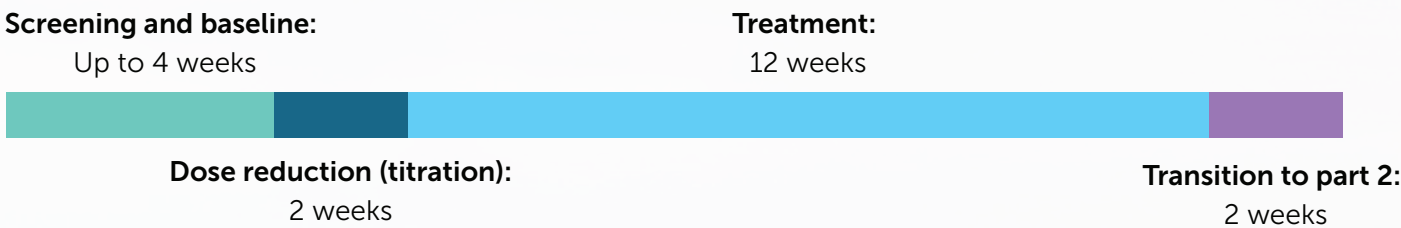
Study participants can continue taking their normal background antiseizure medication(s) during the entire study.

## How long is the GEMZ Study?

The GEMZ Study is a 2-part trial that lasts up to 98 weeks (approx. 2 years) and includes up to 18 visits to the study site.

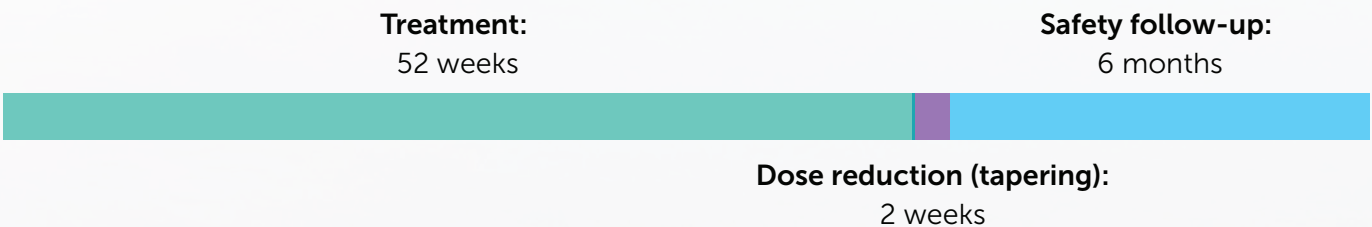
During part 1, participants will be randomized (as if by the flip of a coin) to receive either fenfluramine hydrochloride or placebo (a liquid that looks like fenfluramine but has no medically active ingredients).

This part of the study lasts 20 weeks and includes:



After about 4 months (at least 3 study visits) or completion of part 1, participants may be able to continue to part 2 of the study, where every participant will receive fenfluramine hydrochloride.

Part 2 lasts up to 78 weeks (18 months) and includes:



For details on the study visits, please talk to a member of the study team.

## What are the risks and benefits of joining the GEMZ Study?

The safety of study participants is our top priority, and their health will be closely monitored. Before you decide to join the study, you will receive more information on known side effects of fenfluramine hydrochloride based on previous studies. Participants in the GEMZ Study may find that their seizures don't improve. However, taking part will help increase understanding of the disorder and may pave the way for future treatments.

You will not have to pay for the study medication or any study-related tests or procedures. You do not need insurance to participate. Additionally, reimbursement for study-related travel may be available.

The study team will answer all your questions before you make a decision about the GEMZ Study.





## About clinical studies

By law, a clinical research study (also called a clinical trial) requires many years of carefully supervised research and analysis before a medication may be made available to the public.

- Clinical trials follow strict rules to protect the rights, safety, well-being, and privacy of all participants.
- Study results help determine if a medication is well tolerated and effective in adults and children.
- Clinical trials are the only way to develop new medications to improve healthcare for future generations.

Participating in a clinical research study is a very personal choice, and we encourage you to discuss the GEMZ Study with your current healthcare team.

Taking part in a study is completely voluntary; you can end participation at any time and for any reason, and it will not affect your usual healthcare.

Thank you for your interest in the GEMZ Study for CDD.  
Every participant in a research study makes a valuable contribution  
to research and to learning more about the disease.

Please visit [cddstudy.com](https://cddstudy.com) to learn  
more or contact the study team:

