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TAK-935 (OV935) Clinical Trials

ARCADE

FAQ

1. Will I or my child receive medication during the trial?

The treatment duration for the ARCADE study (also called trial) is 20 weeks.

During this time, you or your child will be taking an investigational medicine (also called investigational drug), TAK-935 (OV935). An investigational drug is one that is not yet approved for use by the Food and Drug Administration (FDA).
During your visits to the study medical center, you and your child will meet with the study team, which will include a doctor, nurse and other healthcare professionals. They will explain the study, answer all your questions, and closely monitor your health or your child's health.

2. Will I or my child need to pay to participate in the trial?

There is no charge if you or your child takes part in the clinical study. The investigational medicine and study-required care plus travel-related expenses and childcare during the visit will be covered.

3. Can I or my child receive any help to get to a site?

We understand the challenges of traveling with a medically complex family member. All study-related travel expenses will be covered. The study coordinator will walk you through the logistics and travel process.

4. What are my obligations for follow up visits?

There will be 7 visits to the study site during the total duration of the study which is 30 weeks.

The study consists of 3 periods:

- 4- to 6-week Screening/Baseline Period
- 20-week Treatment Period
- 2-week taper period and 2-week follow-up

5. What is a phase 2 trial and what does that mean?

ARCADE is a Phase 2 open-label pilot study.

The main goal of a Phase 2 clinical trial is to identify the therapeutic effectiveness of a new study treatment.

The currently approved antiepileptic drugs (AEDs) are sometimes not sufficient to treat epilepsy symptoms in some of the rare epilepsy syndromes.

The main goal of a research study is to learn if the investigational drug TAK-935 (OV935) may help patients such as yourself or your child in the future.

Other key study objectives include examining the safety and tolerability of TAK-935 (OV935) and how it works within the body.

6. If I respond well or if my child responds well what happens when the trial is over?

At the end of ARCADE, you or your child will have the opportunity to enroll into a two-year extension of this study under a separate protocol.

7. What if I don't respond well or my child doesn't respond well?

During the course of the trial, you or your child will be monitored closely by the doctor and study team. If there is ever any concern about your health or your child's health during participation in ARCADE, it is important to contact your doctor immediately. Before deciding to enroll in any clinical trial, you should always consult your doctor.

8. Where are the study sites located?

Below is a list of the study sites and the email of each staff member. If you are interested in learning how to participate in this clinical study, you should contact the site you are interested in:

- Minnesota Epilepsy Group – Kristin Boxwell: kboxwell@mnepilepsy.net
- Massachusetts General Hospital – Kimberly Parkin: kparkin@mgh.harvard.edu
- Boston Children's Hospital – Caitlin Green: Caitlin.Greene@childrens.harvard.edu
- Columbia University Medical Center – Joanne Carroll: JC688@cumc.columbia.edu
- University of California Los Angeles (UCLA) – Careese Stephens: CMStephens@mednet.ucla.edu
- New York University – Sara Rodriguez: Sara.Rodriguez@nyulangone.org
- Children's Hospital Colorado – Courtney Klein: Courtney.Klein@childrenscolorado.org
- Center for Rare Neurological Diseases (Norcross, GA) – Dr. Daniel Tarquinio: daniel@rareneuro.com

9. **What criteria must be met in order to be eligible to participate to the study?**

To participate in the ARCADE study, you or your child must meet the following criteria:

- to have a documented diagnosis of CDKL5 or Dup15q
- to have a parent or caregiver who can provide consent and assent, attend scheduled visits, and participate in study assessments
- to be aged between 2 and 35 years old
- to have an average of at least three motor seizures per month

ARCADE also has other requirements that help ensure the safety of all participants. If you or your child qualifies to participate in the study, these additional conditions will be reviewed with you by the team at your study medical center.