Clinical Trials and Genetic Epilepsy

UNDERSTANDING CLINICAL TRIALS

Researchers conduct clinical trials to identify new ways to prevent, diagnose, and treat genetic epilepsies. In the past, clinical trials have helped people with genetic epilepsy access new anti-seizure medications (ASM), seizure monitors and devices and other innovative therapies. Clinical trials are subject to various regulatory measures to safeguard the safety of participants. Go to Resources for Clinical Trials in Australia to learn more about legislation, regulations and guidelines.

HOW DO CLINICAL TRIALS WORK?

Medical experts always lead clinical trials that investigate genetic epilepsies. Most clinical trials will have a multidisciplinary research team that includes doctors, researchers, nurses, epilepsy support workers and other healthcare professionals. All clinical trials must follow a strict protocol, a set of rules, to help ensure that procedures are adhered to, and safety requirements are met. Most clinical trial protocol designs include:

- The research question, aims, methods, tests and procedures
- Participant eligibility
- The types of interventions and how they will be delivered
- The duration of the clinical trial and what data will be collected

TYPES OF CLINICAL TRIALS

There are many different kinds of clinical trials. The three most common include:

- **Screening:** Investigates new effective genetic testing for epilepsy
- **Prevention:** Studies focusing on the prevention of epilepsies caused by a genetic factor
- **Treatment:** Investigates new ASMs, seizure monitors and devices, surgical procedures or other therapies

PHASES OF CLINICAL TRIALS

All clinical trials have to pass through phases of strict testing. Knowing about each phase is critical as a participant because it will help you understand the potential benefits and risks associated with each study phase. The phases of a clinical trial include:

Pre-clinical: The intervention is conducted on animals to determine their safety and effectiveness.

Phase 1: The treatment is tested for safety and side effects in a small sample of healthy human participants (between 20 and 80).

Phase 2: The treatment is tested for safety and effectiveness in 100 to 400 participants with genetic epilepsy.

Phase 3: The treatment is tested for effectiveness compared to a placebo in a large cohort of participants with genetic epilepsy.

Phase 4: The treatment is tested for long-term adverse side effects after being released for use.

ELIGIBILITY TO PARTICIPATE IN CLINICAL TRIALS

Each individual clinical trial has its own unique inclusion and exclusion criteria. The criteria help set boundaries on who can participate in the clinical trial. By establishing eligibility criteria, the research team can increase the reliability and reproducibility of results and decrease the risk of harm to any potential participant. Some inclusion and exclusion criteria include:

- Age
- Gender
- Type of genetic epilepsy
- Previous seizure treatment history
- Other comorbidities

IMPORTANCE OF CLINICAL TRIALS

Medical experts can use clinical trials to help find out if interventions are effective and safe compared to other existing interventions. In the past, clinical trials have assisted in the following:

- Diagnosing a gene associated with epilepsy
- Decreasing the development of comorbidities

- Helping to treat and manage a person's genetic epilepsy
- Enhancing the quality of life for a person with a complex genetic epilepsy

POTENTIAL BENEFITS AND RISKS

BENEFITS

Clinical trials can help find better treatments, therapies and diagnostic tests for people living with epilepsy. Some of the benefits of clinical trials include the following:

- Improving the quality of life for a person with epilepsy
- Assisting in early diagnosis of a new epilepsy gene
- Helping to identify high-risk groups for developing epilepsy
- Preventing the development of other comorbidities associated with epilepsy
- Helping to find a cure for a rare and complex type of epilepsy

RISKS

There are risks associated with every clinical trial. Participants should speak to their treating neurologist, GP, and the research team conducting the study about all potential risks. These risks include:

- A new treatment may be ineffective or less effective than the current standard treatment.
- A clinical trial could be inconvenient for a participant. This could be due to extensive time commitment.
- A new ASM treatment may have short or long-term side effects.

INFORMED CONSENT

Informed consent is the process by which participants are given all the factual information about a clinical trial before deciding whether they want to participate. Participation in a clinical trial should be completely voluntary and not forced. By signing the informed consent form, the participant agrees to participate in the clinical trial and that they understand the associated procedures and risks of the intervention. A participant can withdraw from a clinical trial during any phase of the

study.

For more information about informed consent, visit:
www.australianclinicaltrials.gov.au/how-be-part-clinical-trial/informed-consent

QUESTIONS TO ASK

Before participating in any clinical trial, it is essential to be well-informed about the study. The research team should answer all questions you have. These may include:

- What is the clinical trial investigating?
- What are the potential treatments that I might receive during the study?
- How does this treatment compare to my current one?
- Are there any potential risks or side effects that I should know about?

- How long does the clinical trial last?
- Where will the clinical trial take place?
- How many in-person visits will I be required to attend at the clinic or hospital?
- What tests will be performed as part of the trial protocol?
- Will I be compensated for my time?

- Can I exit the clinical trial at any time?
- How will the researchers guarantee that my data remains private and confidential?
- Will my GP have access to the results after the clinical trial is complete?
- Once the study is complete, will there be a follow-up with the participants?

FIND A CLINICAL TRIAL

To find epilepsy clinical trials:

- Australian Clinical TrialsClinical Trials – National Institutes of Health
- World Health Organisation Clinical Trials Registry
- Sodium Selenate Treatment for Temporal Lobe Epilepsy – Alfred

LEARN MORE ABOUT CLINICAL TRIALS

- Searching for Australian Clinical Trials
- Clinical Trials Definition – World Health Organisation
- Australian Clinical Trials Alliance