



## Young Person's Information Sheet (aged 13 – 15 years)

Study title: **The EpiNet-First trials of new onset epilepsy**

Locality: **Auckland District Health Board** Ethics committee ref.:14/NTB/56

Lead investigator: **Dr Peter Bergin** Contact phone number:09 379 7440 ext 25663

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### Why is this research study being done?

Epilepsy is a common medical condition in children and teenagers. You are invited to take part in a research study to find out which of several anti-epileptic medicines is best for people who are starting treatment for epilepsy.

### Why me?

You are being asked to take part because you have epilepsy and your doctor has recommended that you start a medicine.

### What will happen to me during the study?

- Your doctor will decide if you need any tests. You will **not** need blood tests or any other samples taken for the study.
- You will receive an anti-epileptic medicine to help stop your seizures. You will receive one of the following medicines: Carbamazepine, Lamotrigine, Valproate or Levetiracetam. Neither you nor your doctor will choose which medicine you will be given, but it will be chosen at random (by a computer). However, once you have been given a medicine both you and your doctor will know which one it is.
- After you have started taking your medicine you will be seen in the hospital clinic. Your doctor will ask your mum or dad or the person who looks after you to write a diary of any seizures that you have.
- We will also ask you some questions about your epilepsy and the medicine you take to treat your epilepsy.
- The study will start in 2014. We plan that over 4000 people (children, teenagers, and adults) will take part in this research study. It will include patients with epilepsy from around the world; we wish to follow up everyone who has taken part in the study for at least 2 years.

### Will the medicines used in this study upset me?

Sometimes medicines upset our body and if this happens we call them 'side-effects'.

Your hospital doctor or epilepsy nurse (their contact details can be found on your seizure diary) will ask you questions in case you do get any side-effects. You will be asked to take one of the following medicines:

## Side effects

Some anti-epileptic drugs may cause dizziness, sleepiness, nausea (feeling sick) or diarrhoea. Sometimes people get clumsy, or have double or blurred vision if the dose is too high. However, many children do not get any side effects from their anti-epileptic medicine, particularly if the medicine is introduced slowly. If side effects do occur, they often settle over the first few days or weeks after a patient starts the drug. Occasionally, anti-epileptic drugs can cause mood changes; sometimes people feel less happy.

If you develop any of the side effects mentioned here, or any other possible side effects, and you are concerned, you should contact your hospital doctor or nurse (contact details can be found on your seizure diary).

## Allergies and hypersensitivity reactions

Some people turn out to be allergic to one or more anti-epileptic drugs. Allergic reactions most commonly happen in the first few weeks after the treatment is started. The most common sign of an allergy is a skin rash. This is most likely with carbamazepine and lamotrigine; approximately one in twenty people will develop a skin rash with these drugs. The rash is usually a minor nuisance, but it can develop into a more severe allergic reaction. If you develop a rash you should contact your hospital doctor or nurse (contact details can be found on your seizure diary). If you cannot get hold of anyone, and you have a rash that is getting worse, you should stop the drug immediately. A severe allergic reaction is more common in Asian patients.

*A full information sheet on the anti-epileptic medicine will be given to you when the doctor prescribes (gives you) the medicine in clinic.*

## Are there any risks to taking part?

There is a risk that some medicines used to treat epilepsy might harm the baby if taken by a girl or woman who is pregnant. If you have periods, your hospital doctor will discuss this further with you.

## Will taking part in this research study help me?

This study might help you. The results of this study might also help us to treat other people with epilepsy.

## Do I have to take part, and can I change my mind?

It's up to you. We only want you to take part if you want to. If you decide to take part and then change your mind, that's OK. You can stop at any time and don't have to say why you want to stop taking part in the study. You do not have to decide today whether or not you will participate in this study. You are able to take as much time as you like deciding whether to participate in the study.

## Who can I ask about this?

You can ask your mum or dad or the person who looks after you. You may want to talk about the study with other people, such as family, whānau or friends. The hospital doctor or epilepsy nurse who gave you this leaflet will also be able to answer your questions. If you need an interpreter, one can be provided, though this may require that you come back to another appointment.

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Dr Peter Bergin, Chairman of the EpiNet study Group  
Consultant Neurologist, Neurology Department, AucklandCityHospital

Phone: 09 379 7440 x 25663

If you require Māori cultural support, talk to your whānau in the first instance. Alternatively you may contact the administrator for He Kamaka Waiora (Māori Health Team) on:

Phone: 09 486 8324 ext 2324

**THANK YOU FOR READING THIS INFORMATION SHEET.  
WE HOPE YOU HAVE FOUND THIS SHEET HELPFUL**



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**Assent Form for young persons (aged 13 – 15 years)**  
*(to be completed by the child and their parent/guardian/carer)*

**Centre Name:**

**Name of Investigator:**

**Trial Number:** | | | | | | | | | |

**Patient's date of birth** | | | | / | | | | / | | | | |

**If you need an INTERPRETER, please tell us.**

**Child (or if unable, parent on their behalf)/young person to tick all they agree with:**

Have you read the information (or had read to you) about the study?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Have you been given enough time to decide whether or not to take part in the study?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Have you had the opportunity to ask whanau/ family support or a friend about the study?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Has someone else explained the study to you?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Do you understand what the study is about?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Have you asked all the questions you want?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Have you had all your questions answered in a way that you understand?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Do you understand that it is OK to stop taking part at any time?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Are you happy to take part in this study?	Yes <input type="checkbox"/>	No <input type="checkbox"/>

If any answers are "no" or you **don't** want to take part, please **don't** sign your name.  
**If you do want to take part, please write your name and today's date:**

**Your Name** \_\_\_\_\_ **Date** \_\_\_\_\_

**Your parent or guardian or carer must write their name here too if they are happy for you to do the study:**

\_\_\_\_\_ **Name of parent/guardian/carer**      \_\_\_\_\_ **Signature**      \_\_\_\_\_ **Date (dd-mm-yyyy)**

**The researcher who explained this study to you needs to sign too:**

\_\_\_\_\_ **Researcher**      \_\_\_\_\_ **Signature**      \_\_\_\_\_ **Date (dd-mm-yyyy)**