

Information Sheet for Parents or Guardians

Epilepsy Research using the Internet; an International Pilot Study Collection of information about seizures and treatment via the Internet

Principal Investigator: Dr Peter Bergin, Neurologist, Auckland City Hospital 09 379 7440 x 25663
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Your child is invited to take part in a research study about epilepsy and seizures. In this study, information will be collected over the Internet, and stored in a database. Please take your time to think about it and decide whether you wish your child to take part. You do not have to give permission, and if you choose not to, it will not affect the management of your child's seizures at all.

Why are you being asked? – What is it all about?

There are many drugs which are available to treat patients with seizures or epilepsy. All of these drugs have been shown to be effective in reducing the likelihood of seizures, though they do not prevent all seizures in all patients. Indeed, some drugs seem to have very little effect in some patients.

Unfortunately, doctors often cannot predict which drug will work best for a particular person.

We hope to undertake studies to learn more about which of the various anti-epileptic drugs work best in different sorts of seizures. We think this can be done by using the Internet to gather information and coordinate drug studies. At this stage, the major focus of our research is to check whether patients can be registered and followed via the Internet. We are now undertaking an International pilot study to check if this is practical; once we have demonstrated this approach works, we will be able to arrange studies in which drugs are directly compared with one another.

What happens during the study?

If you give permission, we will ask your doctor to fill in a form via the Internet to tell us:

- what sort of seizures your child has
- how often his / her seizures occur
- what investigations (scans and EEGs) your child has had
- what drugs your child is using or has already used
- when your child's drugs are changed.

Information will be transmitted over the Internet using secure connections, similar to that which is used by banks. We will collect the following information about your child:

- name
- date of birth
- sex
- ethnicity
- hospital number.

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Confidentiality

We need to collect this information so that we can be sure that we do not mix your child up with anyone else. However, this information will not be made available to anyone else, unless you allow other New Zealand doctors who are taking part in this International Pilot Study to have access to it.

No material which could identify your child will be used in any reports on this study.

Risks and Benefits

Your child will not be put at any risk by taking part. However, all anti-epileptic drugs do carry some risk of side effects, but these risks are neither increased nor reduced by taking part in this study.

There will be several benefits that will result from your child taking part in this study:

- 1) We will learn more about the different types of seizures and epilepsy that occur in New Zealand and in other countries, and how people are being treated here and overseas.
- 2) We will find out more about the areas of greatest uncertainty in the management of epilepsy. This will enable us to design further studies to clear up some of these areas of uncertainty.
- 3) All the information that your doctor enters about your child will be available to the doctor in summary form when your child returns to a clinic. This will help with the ongoing management of his / her seizures, since the doctor will not have to search back through old notes and letters to see when he / she had particular investigations and what drugs have used previously or how effective they were. This information will be immediately available once the doctor logs on to the Internet site once again.

Participation

Your child's participation is entirely voluntary (your choice, and if appropriate your child should also agree). If you do give permission, you will be free to withdraw your child from the study at any time, without having to give a reason, and this will not affect your child's future health care. If you withdraw your consent, we will then stop collecting any information about your child and his / her seizures.

There will not be any costs to you for participating.

You are able to take as much time as you like deciding whether your child should participate in the study.

Your child's treatment will not be changed as a result of taking part in this study. Your child's doctor, after discussion with you, will make the best decisions he or she can regarding the management of your child's seizures. We would like to find out what happens as a result of these decisions, and we are seeking your permission to collect this information.

Future Studies

This study is a pilot study. We will collect information on patients from many countries around the world, and we will store this information in a secure database for 18 months. If you agree for your child to take part in this study, you and your child will not be committed in any way to take part in any further study. However, we hope that this pilot

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study will be followed by further studies in which we will compare different drugs or combinations of drugs, or study other aspects of the management of patients with epilepsy.

You have the option of requesting that your child's information be deleted from the database at the completion of the pilot study, or that it be kept in the database to see if your child may be suitable for any future studies. (Your child's information will automatically be kept in the database unless you or your child tell us that you do not want it kept.)

If you do choose to let us keep your child's information in the database, you and your child will not be committed to taking part in any future trials. You and your child will still be free to withdraw from the study at any time, without having to give a reason, and this will not affect your child's future health care.

If we find that your child is eligible for a future trial, then we will give you further information about that study, and you will have plenty of opportunity to consider whether or not to participate. We will not be asking your child to use any experimental treatments or new drugs.

General Information

If you wish, you may ask a friend, family or whanau member to help you understand the risks and / or benefits of this study and any other explanation you may require. If you need an interpreter, one can be provided, though this may require that you come back to another appointment.

Who should I contact if I have further questions?

If you have any questions about the study, do not hesitate to contact the principal investigator, Dr Bergin, or the local coordinator for this study (listed below), or your local neurologist.

If you have any queries or concerns regarding your rights as a participant in this study you may wish to contact a Health and Disability Advocate, telephone

- Northland to Franklin 0800 555 050
- Mid and lower North Island 0800 42 36 38 (4 ADNET)
- South Island except Christchurch 0800 377 766
- Christchurch 03 377 7501

This study has received ethical approval from the Multi region Ethics Committee which reviews National and Multi Regional studies, ref: MEC/09/02/016

Thank you for reading and considering this information.

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