

Information Sheet for Children

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

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You are 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. You do not have to take part. You can say “No” if you are unsure about the study.

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

We do not always know which is the best drug to use to treat children with epilepsy.

This study is designed to find out more about which medicines work best in different sorts of seizures. We are also testing whether doctors can use the Internet to do these sorts of studies.

We are now doing what is called a “pilot study” along with doctors in other countries to see if we can collect information about epilepsy using the Internet. If this works, we will be able to arrange other 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 you have
- how often your seizures occur
- what investigations (scans and EEGs) you have had
- what drugs you are using or have already used
- when your drugs are changed.

We hope that this will give us a clearer picture of what drugs work best for particular types of seizures.

We will collect the following information about you:

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

We need to collect this information so that we can be sure that we do not mix you up with anyone else. However, only the doctors treating you will be able to get this information.

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Risks and Benefits

You will not be put at any risk by taking part. However, all medicines do carry some risk of side effects. These risks are not increased or reduced if you take part in this study.

If you take part, then ...

- 1) We will learn more about the different types of seizures and epilepsy that occur in New Zealand and in other countries.
- 2) We will be able design further studies to learn the best way to treat patients.
- 3) All the information that your doctor enters about you will be available to the doctor when you come back to a clinic. This information will be immediately available once the doctor logs on to the Internet site again.

Participation

Your participation is entirely voluntary (your choice). You can withdraw from the study at any time, without having to give a reason. If you ask us to, we will stop collecting any information about you and your seizures.

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

In the study we are doing now, we will collect information on patients from many different countries, and we will store this information for 18 months.

You can choose to have your information removed from the database after the pilot study is finished, or you can let us keep it in the database to see if you may be suitable for any future studies. (Your information will automatically be kept in the database unless you or your parents or guardian tell us that you do not want it kept.)

Future Studies

You may be able to take part in another study in the future, if you want to. If this is the case, then we will give you more information about that trial, so that you can decide if you want to take part.

You do not have to take part in any studies.

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.

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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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