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A study of Standard and New Antiepileptic Drugs – SANAD-II

INFORMATION SHEET FOR YOUNG PERSON'S AGED 13 - 15 YEARS
Version 2.0 Dated 28/05/2012

Why is this research study being done?

Epilepsy is a common medical condition in children and teenagers. Recently, a number of new anti-epileptic medicines have become available to treat epilepsy. We want to compare standard and new anti-epileptic medicines for epilepsy to try and find out which are the best.

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 receive either the 'standard' medicines, called *lamotrigine* and *valproate*, or the 'new' medicines, called *levetiracetam* or *zonisamide*. Which medicine you will get will be chosen at random (by a computer). Neither you nor your doctor can choose which medicine you will be given. 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 fits 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 2012. We plan that at least 1,500 children, young people (teenagers) and adults will take part in this research study!
- We will ask if you want to give some of DNA that will help us better understand epilepsy and how it is treated.

What is a DNA and why do you need my DNA?

DNA is the genetic instructions we all have that makes us who we are. Our DNA might also explain why we have epilepsy and also why some medicines work better than others at treating epilepsy.

You will only be asked to give DNA once. We hope to obtain the DNA by a blood test. The blood would be taken using a needle and by a doctor or nurse. We would need about 10mls – the same as two teas spoons – of blood. If you do not want and cannot give a blood sample, we would ask you to give 5mls – the same as one tea spoon – of saliva (spit).

Even if you decide you do not want to give us a DNA sample, you can still take part in the study.

Will the medicines used in this study upset me?

Sometimes medicines upset our body and if this happens we call them 'side-effects'. The medicines used in this research study have been given to lots of children before. Only a few children will get side-effects with the anti-epileptic medicines that will be used in this study.

Your hospital doctor or epilepsy nurse (their contact details are at the end) will ask you questions in case you do get any side-effects.

LAMOTRIGINE ("standard" medicine):

- Possible side effects may include any one of the following: headache, feeling dizzy or sleepy, clumsy and sick, or experiencing double or blurred vision.
- Approximately one in twenty people may develop an allergic reaction (rash) to the drug. Rash could happen usually 2-4 weeks after starting the medicine. If you get a rash you should stop the drug immediately and contact your hospital doctor or epilepsy nurse.
- Lamotrigine and the combined oral contraceptive pill can react together.

VALPROATE ("standard" medicine):

- Possible side-effects include nausea (feeling sick) and diarrhoea. They are more likely to occur at the start of treatment. If they continue for more than 2 or 3 weeks, you or your parents should contact the hospital doctor or epilepsy nurse.
- This drug can cause some people to put on weight and at high doses some people may notice a shakiness of the hands. Occasionally it can cause some loss of hair. The hair will nearly always grow back but it may be thinner.
- Valproate and the combined oral contraceptive pill do not react together.
- If possible, valproate should not be taken during pregnancy.

LEVETIRACETAM ("new" medicine):

- It has only very few side-effects. These include dizziness, mood changes and, rarely, weight changes. Some patients may also develop headache, sleepiness and tiredness.
- Levetiracetam and the combined oral contraceptive pill do not react together.
- There is some evidence that this anti-epileptic medicine has only a small risk of causing abnormalities to the developing baby.

ZONISAMIDE ("new" medicine):

- Possible side effects include dizziness, loss of appetite and weight loss, mood changes, poor memory, sleepiness, double vision and, rarely kidney stones.
- Zonisamide and the combined oral contraceptive pill do not react together.
- There is no good evidence to tell about risks in pregnancy.

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?

If you give DNA from a blood sample you might have a small bruise. However, this is not very common and if a bruise does happen, it usually goes after a few days.

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 children with epilepsy.

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

It's completely 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.

Who can I ask about this?

You can ask your mum or dad or the person who looks after you. The hospital doctor or epilepsy nurse who gave you this leaflet will also be able to answer your questions.

Please Contact: < Insert Name and Title>
<Telephone Number>
Or Contact: < Insert Name and Title>
<Telephone Number>

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



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Assent Form for Young Person’s (aged 13-15)
Version 2.0 Dated 28/05/2012

(to be completed by the child and their parent/guardian/carer)

Centre Name: <insert>

Centre Code: <insert>

Name of Investigator: _____

Study Number: |_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|

Patient’s date of birth |_|_|/|_|_|/|_|_|_|_|_|

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

- Have you read the information (or had it read to you) about this study? **Yes/No**
- Has somebody else explained this study to you? **Yes/No**
- Do you understand what the study is about? **Yes/No**
- Have you asked all the questions you want? **Yes/No**
- Have you had your questions answered in a way you understand? **Yes/No**
- Do you understand it’s OK to stop taking part at any time? **Yes/No**
- Are you happy to take part in this study? **Yes/No**
- Optional: Are you happy to give a DNA sample? **Yes/No**

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 or guardian or carer Signature Date (dd-mm-yyyy)
The researcher who explained this study to you needs to sign too:

Researcher Signature Date (dd-mm-yyyy)

When completed, 1 (original) to be kept in medical notes, 1 for parent, 1 for researcher site file;
1 for the Coordinating Centre, University of Liverpool