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

INFORMATION SHEET FOR CHILDREN AGED 8 - 12 YEARS  
Version 2.0 Dated 28/05/2012

### What is a research study?

A research study is what doctors do when they want to learn about something or find out something new.

### Why is this research study being done?

Epilepsy is a common problem in children. We want to look at 'standard' and 'new' medicines for epilepsy in children to find out which ones are best.

### Why me?

You have been asked to take part in this research study because you have epilepsy and your doctor has given you medicine.

### What will happen to me in 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.
- 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.

We will only take your DNA once. The DNA will be taken by a blood test. The blood will be taken using a small needle and by a doctor or nurse. If you do not want us to do a blood test, we will ask you to give us a bit of your saliva. This will be done by asking you to spit into a small pot.

If you do not want to give a DNA sample, this is OK. You can still take part in this research study.

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

The medicines used in this study have been given to lots of children before. Sometimes medicines upset our body. We call this upset 'side-effects'.

Side-effects do not always happen. If they do happen, they are not usually serious and do not usually last for long. Your hospital doctor or epilepsy nurse will ask you questions in case you do get some side-effects.

*A full information sheet on the 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.

### **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 would like to take part and then change your mind that is OK. You can stop at any time and don't have to say why you want to stop.

### **Who can I ask about this study?**

You can ask your mum or dad or the person who looks after you. The hospital doctor or epilepsy nurse who gave you this information sheet can also 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.**

