Study of emergency treatment of seizures in children

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Parent/Legal Representative Information Sheet

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We would like your permission to use your child/relative's information in a research study

We are doing a study (called EcLiPSE) to find out whether children and young people with long lasting seizures should be treated with phenytoin or levetiracetam (brand name Keppra) in an emergency setting.

Before you decide if you want to give your permission for your child/relative's information to be used in this study it is important for you to understand why the research is being done.

Please take the time to read the following information carefully. Discuss it with friends and relatives if you wish.

You are free to decide whether or not you wish for your child/relative's information to be used.

Please contact the nurse or doctor who has sent you this information sheet if there is anything that is not clear or if you would like more information.

Important things that you need to know

- When your child/relative was brought to the Emergency Department they were having a long lasting seizure.
- Long lasting seizures are a medical emergency and need to be treated without delay.
- It was important to stop your child/relative's seizure as quickly as possible.
- As this was a medical emergency your child/relative was given there was no time to delay their treatment.
- Phenytoin and Keppra are not new and are already used in the treatment of children and young people who have seizures.
- A small amount (2ml) of your child/relative's blood was taken to measure the amount of medicine in their blood stream. This would have happened as part of their care if they had not taken part in the study.

How to contact us

If you have any questions please contact:

Research Nurse: <insert name>
Telephone: <insert number>

Principal Investigator: <insert name>
Telephone: <insert number>

1) Why are we doing this study?

We want to find out whether children and young people with long lasting seizures should be treated with phenytoin or Keppra as it is currently not known which medication is better. This kind of study is the best way of finding out.

This hospital is one of about 30 that is taking part in this study across the UK. The study will involve approximately 300 children and young people.

2) What do I need to know about the medicines used in this study?

Phenytoin and Keppra are not new and are already used in the treatment of children and young people who have seizures or convulsions.

The medicine usually given to children and young people is phenytoin. This medicine has been used to treat children and young people in this way for many years and your child/relative would have received phenytoin as part of their routine care. Phenytoin will usually stop the seizure in just over half of the children and young people who receive it. This medicine has to be given slowly and carefully because it can cause serious side-effects that may affect the heart, blood pressure and skin.

Keppra is another medicine that is commonly used to help prevent seizures in children and young people. It has been used occasionally in the emergency setting for children and young people with long lasting seizures. Studies of Keppra in adult emergency situations suggest that it may be an alternative useful medicine to phenytoin. Keppra can be given to your child/relative more quickly than phenytoin. No serious side effects have been reported with the use of Keppra, but it may cause mild sedation, agitation, or a skin reaction including swelling of the tongue and lips and/or a red itchy rash.

3) How was it decided which medicine my child/relative received?

In this study your child/relative had an equal chance of receiving either phenytoin or Keppra. Outside of the study your child/relative would have received phenytoin. When your child/relative was having a prolonged seizure the doctor or nurse opened a numbered envelope to find out which medicine your child/relative would receive. This had been previously decided by a computer programme.

4) Why am I being asked *after* my child/relative was given the medicine rather than before?

As this was a medical emergency we could not delay giving the medicine your child/relative needed. Explaining the study to you in advance would cause a delay in giving your child/relative urgent medicine. We are now asking for your permission to collect information for the study about your child/relative's hospital stay. This information will help the study team find out which of the two medicines works best to safely stop seizures.

5) What will happen next?

We will collect anonymised information about your child/relative's health and hospital stay, which will be sent to the study centre at The University of Liverpool where it will be held securely up to a maximum of 25 years. Anonymised means that the information will not include your child's name, age or address. We will also ask you to complete a short questionnaire 14 days after your treatment and your child's/ relative's blood sample may be sent to a central laboratory at University Hospital Llandough for analysis.

If you do not agree for your child/relative's information to be used it will be removed from the study. If you do give permission you can still change your mind at any time by contacting the research team using the details on the first page of this sheet. The study results will be made available on the study website when the study is finished: www.eclipse-study.org.uk

6) Who is involved in this study?

The study will take part in Accident and Emergency Departments across the country and is funded by the National Institute for Health Research's HTA Programme (Ref: 12/127/134). The study has been reviewed by a research ethics committee, who have agreed the study is being conducted in a correct and appropriate manner. Alder Hey Children's NHS Foundation Trust and The University of Liverpool are organising this national study. The research team is qualified to do this study because they have all the specialties and skills needed for the study. The team has a lot of experience in caring for children and young people with seizures and are very active in health research. Parents of children and young people with seizures have been involved in the development and management of this study.

NHS
National Institute for Health Research

7) What is the 'Consent' study?

We wish to learn from your experiences of EcLiPSE and also being asked to provide consent *after* treatment had been given to your child/relative. We have called this the 'Consent' study. Your views and experiences are very important to us. This is separate from your decision to allow the use of your child/relative's information in EcLiPSE. As part of the 'Consent' study, a researcher from the University of Liverpool would like to talk to some parents by telephone. These telephone calls will last about 60 minutes. The researcher will ask you how you felt about the EcLiPSE consent process, why you did or did not provide consent and how you think consent should be sought for similar studies in future. This study will inform how we ask other parents about EcLiPSE and future children's emergency research.

Please tick and initial the boxes on the consent form and provide your contact details if you would like to take part in the telephone calls. All information collected will be kept confidential and held securely. Interviews will be professionally transcribed by a company called Voicescript.

If you have any questions about the Consent study please contact: Dr Kerry Woolfall Tel: 0151 794 4634, Email: consent@liverpool.ac.uk

8) What if there is a problem?

Complaints: If you have a concern about any aspect of EcLiPSE, you should ask to speak with the researchers who will do their best to answer your questions (contact details on the first page of this information sheet). If you remain unhappy and wish to complain formally or would like to discuss the study with someone independent of the research team then you can contact your local NHS Patient Advice and Liaison Service (PALS). Details can be obtained from the hospital you attended.