

ECLIPSE Study

EmergenCy treatment with Levetiracetam (keppra) or Phenytoin in Status Epilepticus

Patient Information Sheet

Why are we doing this study?

Most seizures and convulsions in children last less than three minutes and will stop on their own. However, some seizures last longer and become a medical emergency. When this happens it is important that children receive medical help without delay.

When your child was brought to the Emergency Department they were having a seizure and given a medicine called a benzodiazepine. As this medicine did not stop their seizure they needed to be given another medicine often called a rescue medicine which is given via a vein. The rescue medicine routinely given is phenytoin. This medicine has been used to treat children in this way for many years. Phenytoin will usually stop the seizure in just over half of the children who receive it. This medicine has to be given very carefully because it can cause very unpleasant and serious side-effects that may affect the heart, blood pressure and skin. Your child would have received phenytoin routinely within this hospital if the seizures had not stopped.

Levetiracetam (brand name Keppra) is another medicine that is commonly used to help prevent seizures in children. Studies of Keppra in adult emergency situations suggest that it may be an alternative rescue medicine to phenytoin. It has been used occasionally in the emergency setting as a rescue medicine for children. Keppra can be given to your child more quickly than phenytoin. There have been no major side effects reported with the use of Keppra. However, it may cause mild sedation and agitation. We are doing this study to find out whether children should be treated with phenytoin or Keppra in the future. This hospital is one of many taking part in this study across the country and we will be involving 340 children.

At this hospital each child who needs rescue medicine would normally receive phenytoin. Instead, in this study they have an equal chance of receiving either phenytoin or Keppra. This has been predetermined by a computer programme. The doctor or nurse will open a numbered envelope to find out which rescue medicine your child will receive. As this is a medical emergency there is no time to delay giving the rescue medicine your child needs. Explaining the study to you in advance would cause a delay in giving your child urgent medicine. We will come and talk to you about the study as soon as possible after your child is in a stable condition. We will ask for your permission to collect information for the study about which medicine your child received and about their hospital stay from their medical notes. This information will help the study find out which of the two medicines works best to safely stop seizures.

What will happen after your child has received the medicine?

All children will continue to be treated according to local practice. The doctors and nurses will continue to monitor your child closely. If you agree to the use of your child's data in the study we will collect information about your child's health and hospital stay from their routine hospital medical records. This data will be anonymised before being sent to the study centre at The University of Liverpool. The data will be held securely with restricted access. If you do not agree, your child's data will not be used in the study. This will not change the care they will receive. You can change your mind at any time and can contact the research team using the contact details at the bottom of this sheet. The study results will be made available on the study website when the study is finished: {insert link to website}



What if there is a problem?

Complaints: If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your questions {Insert PI/RN Tel no.}. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital.

Harm: In the event that something does go wrong and your child is harmed during the study, and this is due to someone's negligence then you may have grounds for a legal action for compensation against {insert name of NHS Trust}. The normal NHS complaints mechanisms will still be available to you. If it is not due to someone's negligence, compensation may be available through The University of Liverpool (sponsor of the study). In both cases you may have to pay your legal costs.

Who is involved in this study?

Alder Hey Children's NHS Foundation Trust and The University of Liverpool are organising this national study. The study will take part in Accident and Emergency Departments across the country. The Department of Health is funding the study. The study has been reviewed by a research ethics committee, who have agreed the study is being conducted in a correct and appropriate manner. The research team is qualified to do this study because it includes all the specialties and skills needed. The team has a lot of experience in caring for children with seizures and epilepsy and is very active in health research. Parents of children with epilepsy have been involved in the development and management of this study.

For more information or if anything is not clear, please contact

ResearchNurse....., Tel:.....

Principal Investigator....., Tel:

{Add hours of availability and relevant contact details for each site}