

ECLIPSE Study

Emergency treatment with Levetiracetam or Phenytoin in Status Epilepticus

Patient Information Sheet

Most epileptic seizures and convulsions in children last less than three minutes and will stop spontaneously. However, sometimes the seizure may last longer than three minutes.

When your child was brought to the Accident and Emergency Department they were having a seizure and given the anti-epileptic medicine called a benzodiazepine. As this medicine did not stop their seizure they needed to be given another medicine. Your child would have received phenytoin routinely if the seizures had not stopped. This will usually stop the seizure in just over half of the children who receive it. However, it will not stop the seizure in just under half of the children who receive it. In addition, phenytoin has to be given very carefully because it can cause very unpleasant and very serious side-effects that may affect the heart, blood pressure and skin. Some early results of a new anticonvulsant called levetiracetam suggest that it may be more effective and safer than phenytoin; but this needs to be researched further.

In this study, we are looking to see whether phenytoin or levetiracetam is safer and more effective at stopping children's seizures. We are making sure that each child who needs an anti-epileptic medicine (after the benzodiazepine) has an equal chance of receiving either phenytoin or levetiracetam. The doctors and nurses who do the study will know which drug the child is given. We will come and talk to you about the study as soon as possible after the medicine has been given. We will ask for your permission to collect information for the study about the type of 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 is safer and more effective at stopping seizures.

What will happen after your child has received the medicine?

Your child will be cared for according to local practice. The doctors and nurses will continue to monitor your child closely. We will talk to you about the study in more detail at a suitable time for you.

If you decide to continue with the study we will:

- 1) Collect information about your child's health and hospital use from their routine medical records.



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 research because it includes all the specialties and skills needed for the study. The research team has a lot of experience in caring for children with seizures and epilepsy and is very active in health research. Some of the research team have children with epilepsy.

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

Research Nurse..... Tel:.....

Principal Investigator..... Tel: