



## ECUSTEC Parent Letter for Patient Identification Centres

Dear Parent or Guardian,

### **Trial Title: Eculizumab in Shiga-Toxin producing E. Coli Haemolytic Uraemic Syndrome (ECUSTEC): A Randomised, Double-Blind, Placebo-Controlled Trial**

Your child's doctor suspects that they might have a condition known as Haemolytic Uraemic Syndrome (HUS). This is a disorder which can affect the kidneys, causing them to suddenly stop working properly. Your child may be transferred to the children's kidney unit for specialist treatment.

Lots of supportive treatments are available to help your child through this illness, and your doctor will explain which treatments your child needs as necessary. However there is no specific treatment which can tackle the underlying problem.

The children's kidney specialists in the UK are joining together to test a new treatment that might be effective in this form of HUS in a clinical trial called ECUSTEC. If your child is transferred to the children's kidney unit and meets a number of criteria, the kidney specialist may talk to you about ECUSTEC and whether you would like to consider your child participating.

The trial treatment would need to be started within 48 hours of your child being transferred to the kidney unit, and we appreciate that is not much time to make an important decision. We have prepared some information about ECUSTEC for parents and families to help them think about participating, and we would like to share that with you at this stage so that if your child is offered participation you have as much time as possible to consider it. This information can be found on page 3 entitled "Summary of this research trial"

Looking at this information and taking part in the research is entirely voluntary. It is up to you and your decision will not affect the standard of care your child receives. You don't need to make any decisions at the moment and the children's kidney team will talk to you in more detail if your child meets the criteria for ECUSTEC in due course.

Many thanks for taking the time to read this information at this difficult time.

Yours faithfully,

Dr Sally Johnson, ECUSTEC Chief Investigator

Telephone 0191 282 4917

For queries about the trial or for further information please contact:

The ECUSTEC trial co-ordinating centre is located at the Birmingham Clinical Trials Unit, College of Medical & Dental Sciences, Institute of Applied Health Research, University of Birmingham, Edgbaston, Birmingham B15 2TT. Tel 0121 415 9132, Fax: 0121 415 9135, Web address: [www.birmingham.ac.uk/ECUSTEC](http://www.birmingham.ac.uk/ECUSTEC)



### **Summary of this research trial**

Shiga-Toxin producing E. Coli Haemolytic Uraemic Syndrome (STEC HUS) is a sudden illness that develops in some people (often children and young people) after a gut infection caused by bacteria called STEC (Shiga-toxin producing E.Coli). People with STEC HUS often develop acute kidney injury – when the kidneys suddenly stop working properly – and some of these people need dialysis (artificial kidney treatment). Sometimes STEC HUS can cause complications in other parts of the body. Most people fully recover from STEC HUS but some will have long-term consequences and may need long-term specialist care.

Eculizumab is a medicine that blocks part of the immune system that seems to play a part in causing STEC HUS. Some doctors have given eculizumab to people with severe STEC HUS but not in a systematic way that can tell us whether it worked. We are testing eculizumab in a trial to see if it can make STEC HUS better.

The purpose of this trial is to see whether giving two doses of eculizumab to children and young people with STEC HUS reduces the severity of their disease. 134 children and young people with STEC HUS will be selected by kidney specialists at children's kidney units around the UK over a four year period. In addition to their normal care, they will receive either eculizumab or placebo (inactive medicine) within 48 hours of arriving at the kidney unit and a second dose of the same medicine a week later. In order to determine if eculizumab has been effective, information about each child's progress over the following 12 months will be collected by the team at the children's kidney unit.