ECUSTEC Newsletter

Issue 3 | August 2017

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

Short Title: The ECUSTEC trial

Welcome to the third issue of the ECUSTEC Newsletter!

The ECUSTEC trial opened to recruitment on the 10th July 2017!!!

Firstly, we would like to thank all of the ECUSTEC collaborators for supporting the trial. We would also like to congratulate and thank **Dr Sally Johnson and the team** at the **Great North Children's Hospital** and **Prof Moin Saleem and the team** at **Bristol Royal Hospital for Children** who are now **fully approved** to randomise patients into the trial.

ECUSTEC opened to recruitment on the 10th July 2017 and the clock has now started for the pilot phase of the trial. To enable us to continue on to the substantive trial and answer this important research question, **twenty six patients** must be **recruited by July 2018**. Please could sites who are not open to recruitment contact the trials team to finalise site set-up and arrange a site initiation visit (SIV) if one has not yet been arranged.

Design:

Phase II randomised, parallel-group, double blind, placebo-controlled trial.

Aim:

To assess whether Eculizumab (Ecu) reduces the severity of Shiga-toxin producing Escherichia coli Haemolytic Uraemic Syndrome (STEC HUS) in children and young people.

The ECUSTEC trial is supported by the Efficacy and Mechanism Evaluation (EME) Programme, an MRC and NIHR Partnership

NIHR EME Update!!!

The funder are expecting all recruiting centres to be open by November 2017. If it is not likely your centre will be open to recruitment by November 2017 please inform the trials team as soon as possible.

Participating in ECUSTEC	We are pleased to announce we now have **2** centres fully approved to randomise patients into the ECUSTEC trial. The trial will take place in **12** centres across the UK with the assistance of the Clinical Research Network (CRN). Applications are currently in progress from **10** ECUSTEC sites to gain all the necessary permissions to allow the trial to begin at each site. The table below shows the ECUSTEC sites that were included in the initial IRAS applications.

Alder Hey Children's Hospital	**Leeds General Infirmary**
Birmingham Children's Hospital	**Nottingham Children's Hospital**
Bristol Royal Hospital for Children *	**Royal Hospital for Children, Glasgow**
Evelina London Children's Hospital	**Royal Manchester Children's Hospital**
Great North Children's Hospital *	**Southampton Children's Hospital**
Great Ormond Street Hospital	**University Hospital of Wales**
* Site opened to recruitment	

Notices to ECUSTEC Investigators!!!

Site Initiation Visits

The trials team would like to thank all of the staff at ECUSTEC recruiting and patient identification centres (PICs) for your assistance during site set up. If you have not yet arranged a site initiation visit, please contact the trials team (**ecustec@trials.bham.ac.uk**) to arrange.

Site Agreements

The twelve recruiting tertiary centres have now received the model non-commercial agreements. If your centre has any **outstanding queries** regarding site agreements please inform the trials team who will work with you to resolve any outstanding queries.

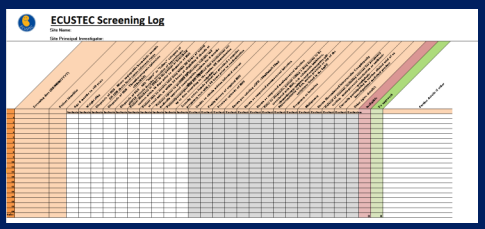
Site Files

Site and pharmacy files have been finalised and will be sent to sites prior to SIVs. If you have not yet received your site and pharmacy files please contact the trials team to finalise set-up at your centre.

Screening Logs

The Trial Management Group (TMG) and Trial Steering Committee (TSC) are monitoring screening data. The trials team will be requesting completed **ECUSTEC Pre-screening and Participant Approach Logs** prior to each meeting. The **up-coming TMG** meeting dates are **26th September 2017** and the **12th December 2017**, the trials team will contact you approximately three weeks before each meeting.

The pre-screening and approach logs can be found in Section 4.1 of the Site File.



ECUSTEC Details:		
Trial Sponsor: The Newcastle Upon Tyne Hospitals NHS Foundation Trust **IRAS Project Code:** 199217		**Funding:** National Institute for Health Research Health, Efficacy and Mechanism Evaluation Programme (NIHR EME). **Ref: 14/48/43**
EUDRACT No: 2016-000997-39 **CTA**: 17136/0282/001-0001 Approval: 3rd January 2017	**REC Ref No.:** 16/NE/0325 North East - Newcastle & North Tyneside 1 Research Ethics Committee Approval: 23rd January 2017	**The ECUSTEC trial has been adopted by the NIHR Clinical Research Network (CRN)**

ECUSTEC Trial Details

ECUSTEC is a randomised, parallel-group, double blind, placebo-controlled trial of eculizumab in 134 children aged 6 months to <19 years, inclusive, with STEC HUS. The trial contains an internal pilot phase of 18 months (12 months recruitment, 6 months follow up) to determine whether the substantive trial will continue.

Need for the ECUSTEC trial

The use of eculizumab for the treatment of severe STEC HUS is increasing internationally, with no objective evidence of efficacy or safety in children, and at huge cost to the NHS and other health services. If the efficacy of eculizumab in STEC HUS is not properly evaluated in a prospective trial, unregulated use will increase until a controlled trial becomes unfeasible. The ECUSTEC trial provides the opportunity to evaluate eculizumab in STEC HUS objectively. If efficacious, this treatment may alter the natural history of STEC HUS, reducing acute mortality, morbidity and long term sequelae. If eculizumab is found to be ineffective, the trial will help to ensure that NHS resources are not wasted.

Follow-up

All participants will be followed-up for 52 weeks. **Daily until discharge** (reducing to weekly after Day 14 if still admitted), then at **30 and 60 days** and then **6 and 12 months** post randomisation.

The EUCSTEC trial team are always here to help.
For further information about the ECUSTEC trial please contact us:

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Thank you for taking the time to read the ECUSTEC Newsletter!!!