

# ECUSTEC Newsletter

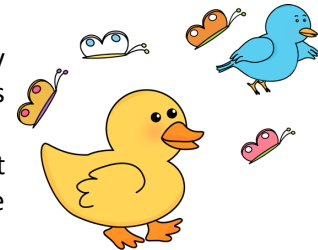
Issue 9, March 2019



## Message from the Chief Investigator

I'd like to thank all of you involved in ECUSTEC for your continued commitment to delivering the trial. We are totally dependent on your support and we appreciate the efforts made in each and every patient approach. As the peak 2019 STEC season approaches, I'd like to share a few thoughts that might help us in our recruitment.

- Why not run a local ECUSTEC refresher session? This will help all team members be confident they are familiar with the inclusion and exclusion criteria and know where to find their study documents at those crucial moments.
- Consider including an ECUSTEC session in any upcoming regional network meetings – an excellent chance for the renal units and patient identification centres to discuss practical issues to facilitate recruitment. I, and other members of the ECUSTEC trial team, would be delighted to join you!
- It may be helpful to know that families that have already taken part in ECUSTEC have given on the whole very positive feedback about their involvement in the trial
- Remember the importance of sending early stool samples/rectal swabs in suspected STEC infection to both your local microbiology lab and to the Public Health England reference laboratory at Colindale



I hope that we can beat our 2018 recruitment figures – we'll keep you up to date with the running total

With my warmest wishes

Sally Johnson

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.

ECUSTEC is funded by the Efficacy and Mechanism Evaluation (EME) Programme, an MRC and NIHR partnership

ECUSTEC is sponsored by The Newcastle Upon Tyne Hospitals Nhs Foundation Trust  
ISRCTN89553116  
EUDRACT: 2016-000997-39

## BCTU Easter Closure & SAE reporting

Birmingham Clinical Trials Unit will be closed from Friday 19th April and re-open on Thursday 25th April 2019. **SAE reporting continues over Easter.**

Whilst BCTU is closed, please e-mail any new SAE reports directly to the Chief Investigator and CC in the trial's NHS.net account. These will be monitored.

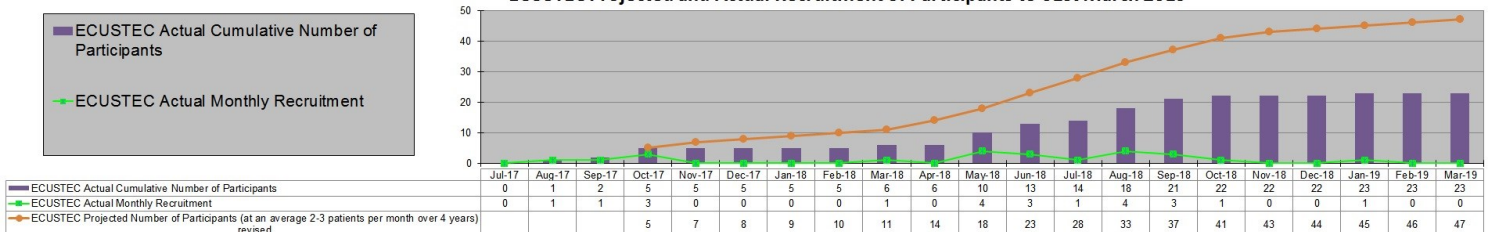
sally.johnson15@nhs.net      [Ecustec.Trial@NHS.net](mailto:Ecustec.Trial@NHS.net)



## Recruitment

Since ECUSTEC opened on the 10th July 2017, 23 patients have been recruited to the trial and we are pleased to announce that 12 centres are now open to recruit patients with Alder Hey Children's Hospital being the latest site to be fully approved on the 14th January 2019. We would like to congratulate and thank Dr Aoife Waters and the team at the Great Ormond Street Hospital for randomising the 23rd patient into the trial.

ECUSTEC Projected and Actual Recruitment of Participants to 01st March 2019



## Patient Identification Centres

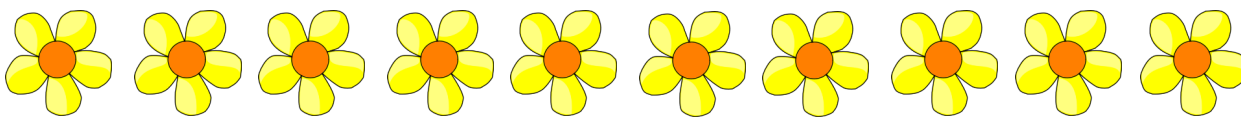
Thank you to all of the teams at ECUSTEC PICs for supporting and facilitating recruitment into ECUSTEC. We are continuing to recruit secondary care centres throughout the UK and the Trials Team are continuing to initiate contact with potential PICs. If you are aware of any colleagues at secondary care centres who are interested in participating as an ECUSTEC PIC please forward their contact details to the Trials Team (ECUSTEC@trials.bham.ac.uk).

## STEC detection

As the new season of STEC HUS (or typical HUS/D+HUS) approaches we are contacting all sites for the ECUSTEC Trial and asking you to raise additional awareness with your respective Emergency & Microbiology departments with the objective of improving STEC detection. A positive STEC result is not an absolute requirement for study entry, but in some cases a positive result can ensure a patient is eligible.

The main things to remember are:

1. Take stool cultures and rectal swabs BEFORE starting antibiotics in possible STEC HUS (NB although antibiotics are not indicated in STEC infection it is appreciated that in the early stages a broad differential diagnosis may apply)
2. Ensuring rectal swabs are taken and at least stored for STEC PCR if cultures are negative.



## Day 30 Stool Sample

These stool samples are sent to Public Health England for analysis for STEC detection. Sites have been having problems locating the results of these samples. If you are missing any Day 30 stool sample results, can you please email the details of the Patient with dates sample sent to Claire Jenkins at PHE, who will be able to send the result to you. Her email address is Claire.Jenkins1@phe.gov.uk

## ECUSTEC Screening Information

The Trials Team would like to take this opportunity to thank ECUSTEC recruiting centres for forwarding screening information promptly when requested by the Trials Team, and for informing us of any potential patients. This helps us to monitor the number of patients being screened for the trial, identify any barriers to recruitment and cross-reference against public health screening data.



### Study Contact details

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## Maintaining the Double-Blind

To ensure the trial answers the research question as reliably as possible, please could we remind all site pharmacies and unblinded trial staff to maintain the double-blind and be aware of areas where potential unblinding may occur i.e. financial monthly reports, informing site or trials unit staff about IMP orders.



## Data Returns

The amount of Case Reporting forms we have received back at BCTU is extremely good. Out of the 558 forms currently expected, we are only missing 27 forms. With 12 of these being the Stool sample result forms. That is a return rate of 95%

Data Clarification Forms are the way we resolve discrepancies on the CRFs we receive, currently we only have 16 outstanding DCF forms from the 139 forms generated. We would like to thank all the staff at recruiting centres for all their hard work.

Form	Data Return Rate
Baseline CRF	100%
Treatment forms	100%
Initial Admission for Trial Treatment forms	100%
Follow Up CRF	96%
Certificates of Vaccinations	99%
Questionnaires	93%
Data Clarification forms (Critical)	85%
Data Clarification forms (Non-Critical)	96%

## Training for New Staff working on ECUSTEC

Local Changes to Research Staff at Approved Centres: If there are any changes in staff at your site please remember to send us your updated delegation log. If new staff are added to the delegation log, please also forward a copy of their CV (signed and dated within the last 12 months) and their latest GCP certificate. If any new or existing staff would like to arrange one-to-one training about the trial, please contact Emma Barsoum. The ECUSTEC team are always happy to help so please contact us if you have any questions!

### In Other News

- Birmingham Clinical Trials Unit recently celebrated it's 21st Anniversary. Since its inception in 1997, BCTU has supported a wide range of clinical studies across a wide spectrum of clinical conditions and in diverse populations.
- It is with great sadness that we have to inform you that Emma Barsoum has left her role as Trial Manager, and has taken up a new role in the Clinical Trials team at UCL..
- Happy Easter from Terry, Hugh and everyone here at BCTU.

