

ECUSTEC Newsletter

Issue 10, September 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. Here is a summary of the current trial status.

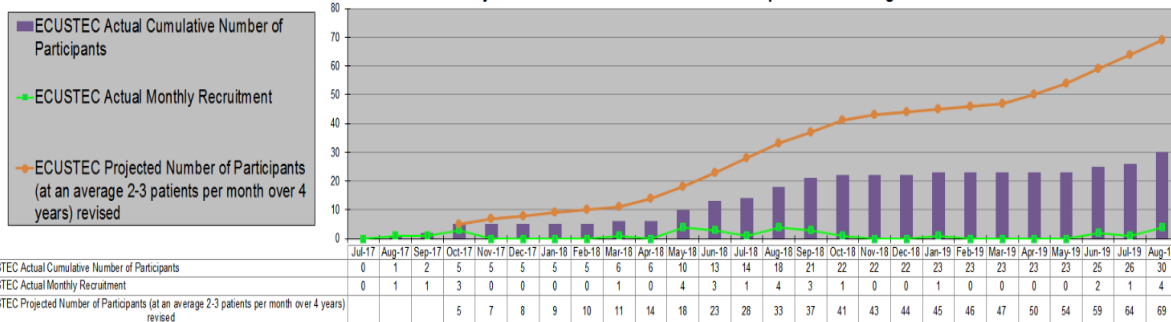
With my warmest wishes,
Sally Johnson

Recruitment

After a slow start to the 2019 season, recruitment has picked up in August. Two patients were recruited in June, one in July followed by four in August. Hopefully we can maintain this over the next few months.

Many thanks to the University Hospital Wales, Qmc Paediatrics Nottingham, Royal Manchester Children's Hospital, Leeds General Infirmary and Bristol Royal Hospital For Children for recruiting the last 7 patients.

ECUSTEC Projected and Actual Recruitment of Participants to 27th Aug 2019



Also I'd like to say a big thank you to Alder Hey Children's Hospital who has accepted a transfer of patient from University Hospital of Wales, this was due to the patient living in the North West of England and was hospitalised during a family vacation. The Cardiff and Alder Hey teams worked together with the Trials Unit to successfully transfer the child between two doses of IMP, allowing the child to continue in the trial. This is a remarkable achievement and well done to all involved. The total number of patients recruited is 30, which is -39 recruitments behind target.

Recruitment issues

Data from Public Health England and Health Protection Scotland shows there has been a fall in the incidence of STEC-HUS over the past 2 years, which has co-incided with the trial opening to recruitment. Therefore for the trial to succeed, it is essential we recruit as many eligible patients as possible. We are exploring a number of aides to help all those in ECUSTEC to achieve this. The first of these, a "Frequently Asked Questions" document has been circulated to teams. Watch this space for more information.

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.

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ECUSTEC is sponsored by The Newcastle Upon Tyne Hospitals Nhs Foundation Trust
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Screening data

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 screen-

Patient Identification Centres Day 30 Stool Sample

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).

These stool samples are sent to Public Health England for analysis for STEC detection. Can I remind sites all Day 30 stool samples should be sent with both the ECUSTEC research sample form and the NHS L5 form to ensure results are received. If you are still missing any Day 30 stool sample results, can you please email (via nhs.net) the Patient details and date of sample to Claire Jenkins at PHE (Claire.Jenkins1@phe.gov.uk) who will send the result to you. Please forward the result to the trial team at BCTU once received.

Maintaining the Double-Blind

Please could we remind all site pharmacies and unblinded trial staff to be aware of areas where potential unblinding may occur i.e. financial monthly reports, informing site or trials unit staff about IMP orders.

ECUSTEC Refresher training

Why not hold a refresher session to keep the Trial in the minds of the team members at your 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 Raquel Fernández del Río (fernandezdelrio@bham.ac.uk).

The ECUSTEC team are always happy to help so please contact us if you have any questions!

Data / Case Report forms

Please ensure that the correct versions of the Trial documentation and CRF forms are used. The current documentation can be found on the [ECUSTEC Website](#).

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Outbreak Planning

STEC HUS can occur in localised outbreaks. It is important that teams are ready to deliver the trial in an outbreak situation and the trial team have focused on outbreak planning recently. At the Great North Children's Hospital the trial has been accepted onto a register of "Hibernation Studies" which means additional resources can be directed in the event of an outbreak (e.g. Influenza studies). Other sites are encouraged to see if a similar system is in place in their Trust.

Certificate of Vaccination

Please may we remind sites to ensure that the Day 1 and Pre-Discharge Certificates of Vaccination are forwarded to both BCTU and Alexion.



STEC detection

As the season of STEC HUS (or typical HUS/D+HUS) is well underway 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 stool samples or rectal swabs are taken and at least stored for STEC PCR if cultures are negative.

Other News

HUS Workshop

We are pleased to announce an exciting and content-rich workshop. The Gastrointestinal Infections team at PHE will be hosting a HUS workshop on 7th November in Birmingham. Ecustec Chief Investigator, Dr. Sally Johnson will present the latest updates on the ECUSTEC trial.



HUS Workshop



Save the date

Ecustec Twitter account

ECUSTEC has a new official twitter account!



Follow us [@Ecustec_BCTU](https://twitter.com/Ecustec_BCTU)

We hope that with this account will be able to communicate the aim of ECUSTEC to a broader audience and to make more people aware of the availability and the potential benefits of being part of this trial and perhaps increase recruitment. The Medical community will have the opportunity to share comments concerning HUS and keep up to date with the latest news on STEC-HUS. Please follow us for frequent updates on everything related to the Trial, please tag it in all your tweets and encourage your colleagues to use it.

ECUSTEC new Trial Manager

Ecustec has a new trial coordinator! My name is Raquel Fernández del Río and I have recently started working as Trial Coordinator for the ECUSTEC trial. I am responsible for the management and administration tasks of the Trial. My most recently role has been working as a Researcher within the Proton Ionisation Molecular Mass spectrometry project in the Molecular physics Group at the University of Birmingham. My work was focussed on finding biomarkers in the breath of cirrhotic patients for the benefit of a non-invasive clinical diagnosis of liver disease procedures and monitoring of Hepatic encephalopathy. I am very enthusiastic to join the Ecustec Team and looking forward to support the trial to find better ways to treat STEC-HUS in the future.

