



ECUSTEC Newsletter



Issue 11, December 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. Recruitment is the biggest challenge for the trial and we are working hard to maximise recruitment against a reduced incidence of STEC HUS at present, so that we can address the very important research question – whether eculizumab reduces the severity of STEC HUS. With my warmest wishes to all ECUSTEC supporters this festive season,

Sally Johnson



Recruitment

The total number of participants currently recruited into the trial now stands at 34, with 10 of 12 Sites having recruited at least one patient. 11 participants were recruited during the STEC-HUS 2019 season, which is slightly less compared to the 2018 season. We would like to thank to Bristol Royal Hospital For Children, Southampton General Hospital, Royal Manchester Children's Hospital and Leeds General Infirmary for recruiting the last 4 participants into the trial. Although the peak STEC-HUS season is over for 2019 we urge sites to be vigilant for potential patients and to continue informing the Trials Team (ECUSTEC@trial.bham.ac.uk) to assist in accurate screening and reporting on progress of the trial. The incidence of STEC HUS has been lower over the past couple of years and it is vital that we try to recruit as many eligible patients as possible.

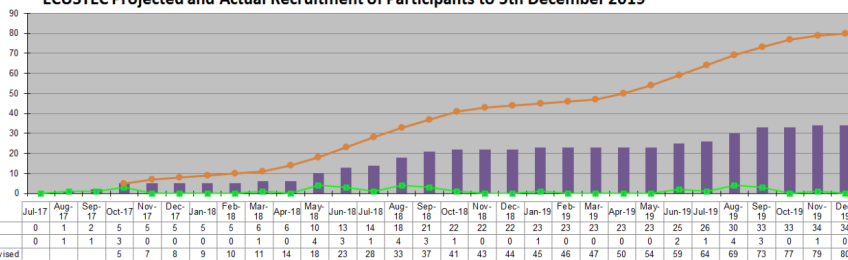
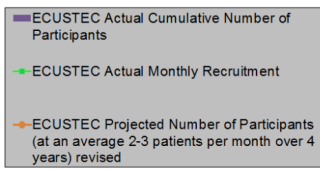
Design:
Phase II randomised, parallel-group, double blind, placebo-controlled trial.

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

ECUSTEC Projected and Actual Recruitment of Participants to 5th December 2019



Month	Actual Cumulative	Actual Monthly	Projected
Jul-17	0	0	0
Aug-17	1	1	1
Sep-17	2	1	2
Oct-17	5	3	5
Nov-17	5	0	5
Dec-17	5	0	5
Jan-18	5	0	5
Feb-18	5	0	5
Mar-18	6	1	6
Apr-18	6	0	6
May-18	10	4	10
Jun-18	13	3	13
Jul-18	14	1	14
Aug-18	18	4	18
Sep-18	21	3	21
Oct-18	22	1	22
Nov-18	22	0	22
Dec-18	22	0	22
Jan-19	23	1	23
Feb-19	23	0	23
Mar-19	23	0	23
Apr-19	23	0	23
May-19	23	0	23
Jun-19	25	2	25
Jul-19	26	1	26
Aug-19	30	4	30
Sep-19	33	3	33
Oct-19	33	0	33
Nov-19	34	1	34
Dec-19	34	0	34

Christmas and New Year Arrangements 2019-2020

Please note that the telephone randomisation service at BCTU and the ECUSTEC Trial Office will be closed from:

1.00pm Friday 20th December 2019 until 9.00am Thursday 2nd January 2020

The online randomisation service will still be available during this time.

SAE Reporting Arrangements Christmas and New Year 2019-2020

SAEs detected during this time should be sent to Dr Sally Johnson as soon as possible after detection by email: sally.johnson15@nhs.net.





Notice to investigators

Patient Identification Centres

Many thanks to all of the teams at ECUSTEC PICs for supporting and facilitating recruitment into ECUSTEC. If you are aware of any colleagues at secondary care centres who are interested in participating as a ECUSTEC PIC please forward their contact details to the Trials Team (ECUSTEC@trial.bham.ac.uk)

Maintaining the Double-Blind

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

Training for New Staff working on ECUSTEC

If there are any staff changes or new staff are added to the delegation log, please remember **to send us 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 (ECUSTEC@trial.bham.ac.uk) the ECUSTEC team are always happy to help.

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**.

Day 30 stool Sample

These stool samples are sent to Public Health England for analysis for STEC detection. Can I remind sites all new stool samples should be sent with the **ECUSTEC research sample form and the NHS L5 form** as well, this seems to help with the return of the samples as previously we have been encountering problems getting the results. Any Sites still 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.

STEC DETECTION

Although the STEC-HUS season is now over 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.

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](#).

Study Contact details

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Screening data

Many thanks to the ECUSTEC recruiting centre for forwarding screening information promptly when requested by the Trials Team, and for informing us of any potential patients. This help us to monitor the number of patients being screened for the trial, identify any barriers to recruitment and cross-reference against Public Health England.

Data Collection

Data return rates remain good with approximately 93% of all due forms returned to date.

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 a outbreak.

Protocol release

The amendment version 4.0 has received approval from the HRA, MHRA and REC and will be implemented before end of this year. Protocol 5.0 will be released next year.

ECUSTEC TWITTER:

ECUSTEC has recently opened a twitter account. Please keep an eye on twitter and follow us for Trials updates and encourage your colleagues to use it!

Follow us @Ecustec BCTU



STEC-HUS Workshop:

Many thanks to Public Health England for organizing this valuable workshop in STEC-HUS in Birmingham, the event was a big success. Thank you to all the attendees and speakers for their contribution and for bringing their expertise and experience in STEC-HUS. During the workshop the panel proposed ideas on how to improve HUS management and diagnosis. The photo below shows our Chief Investigator during the workshop. For those who could not attend the workshop, they can request us the slides r.fernandezdelrio@bham.ac.uk. We hope to see you all next year!



Sally Johnson, ECUSTEC Chief Investigator, giving a talk on the importance of STEC diagnosis in HUS management during the STEC-HUS workshop in Birmingham.

ECUSTEC WEBSITE:

A reminder that on the ECUSTEC website <https://www.birmingham.ac.uk/research/activity/mds/trials/bctu/trials/renal/ECUSTEC/index.aspx> are uploaded the trial documents. Please check the website as it is often updated with the latest news on the trial.

The trial team would like to thank the ECUSTEC Team and colleagues for all their hard work during the 2019 season and support on the trial and wishes you a nice a warm holiday season and Happy New Year 2020!



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