

ECUSTEC Trial: Review of Progress

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ECUSTEC Senior Trial Manager



ECUSTEC Overview



Birmingham Clinical Trials Unit

- Trial coordination
- Data collection
- Data analysis
- Design and maintenance of the trial website and database
- Randomisation
- Safety reporting

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The Newcastle upon Tyne Hospitals NHS Foundation Trust

- Chief Investigator
- Sponsor
- Oversight
- Trial design
- Clinical lead



- ❑ Sponsor: The Newcastle upon Tyne Hospitals NHS Foundation Trust
- ❑ Chief Investigator: Dr Sally Johnson
- ❑ Deputy Investigators:
 - Prof Nicholas Webb, Manchester University Hospitals NHS Foundation Trust
 - Prof Moin Saleem, University Hospitals Bristol NHS Foundation Trust
- ❑ Coordinating Centre: Birmingham Clinical Trials Unit (BCTU)
 - Hugh Jarrett, Team Lead
 - Emma Barsoum, Trial Manager
 - Terry Hughes, Data Manager



ECUSTEC Overview



- ❑ Trial Design: Randomised, parallel group, double blind, placebo-controlled trial
- ❑ Sample size: 134 patients
- ❑ Full trial: 6 years
 - 6 months set-up
 - 4 years recruitment
 - 1 year follow-up
 - 6 months final data cleaning and analyses
- ❑ Pilot study incorporated



ECUSTEC Sites



- ❑ Tertiary centres
 - Participating as recruiting centres: **12**
 - Open to recruitment: **10**

- ❑ Great North Children's Hospital was the first site open to recruitment on the **10th July 2017**

- ❑ Patient Identification Centres (PICs)
 - Confirmed Capability and Capacity (C&C): **66**
 - PICs: **over 100 contacted**



ECUSTEC PICs



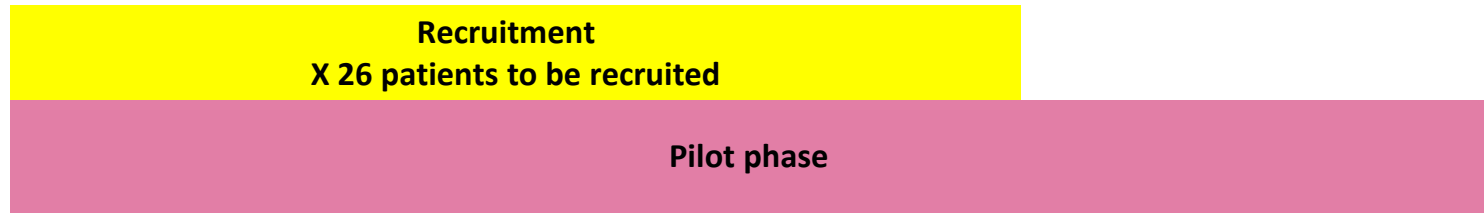
Site name	Number of confirmed PICs
Alder Hey Children's Hospital	4
Birmingham Children's Hospital	1
Evelina Children's Hospital	4
Great Ormond Street Hospital	10
Great North Children's Hospital	8
Leeds General Infirmary	5
Nottingham Children's Hospital (QMC)	15 (1 site subsequently withdrawn)
Royal Hospital for Sick Children, Bristol	5
Royal Hospital for Sick Children, Glasgow	3
Royal Manchester Children's Hospital	7
Southampton Children's Hospital	3
University Hospital of Wales, Cardiff	2



ECUSTEC Pilot Phase



Jul 17	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul 18	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar
17	17	17	17	17	17	18	18	18	18	18	18	18	18	18	18	18	18	19	19	19



- Pilot phase started on the date the 1st patient was randomised – 11th August 2017
- Pilot recruitment phase is due to end after the 2018 STEC HUS season
 - DMEC will meet to review pilot data
 - Assess safety and tolerability



ECUSTEC Pilot Phase



Stop/Go point is March 2019

26 patients to be recruited

20 of the 26 patients to have received the planned two doses of trial treatment

At least 22 of the 26 patients to complete 6 months follow-up

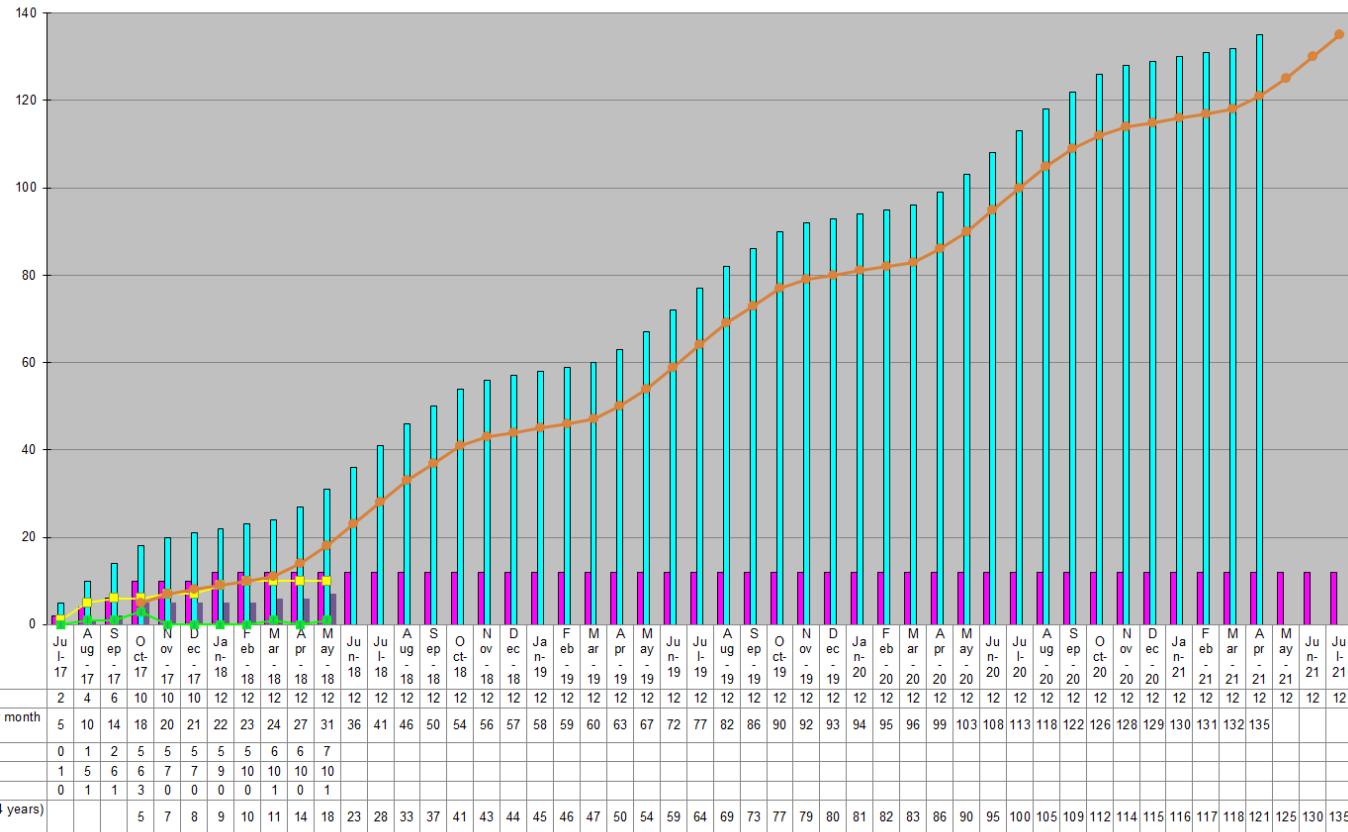
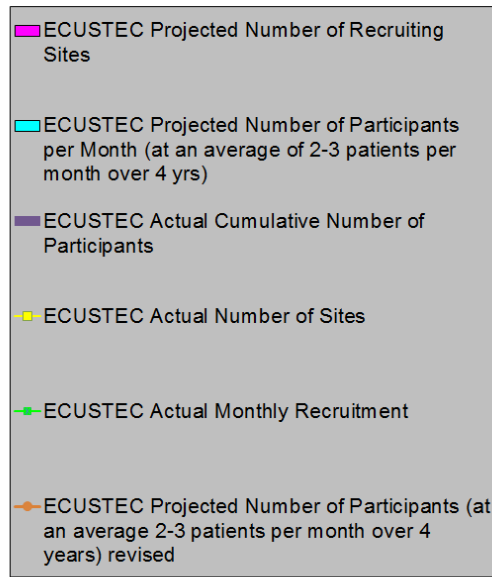
Also a progress report due November 2018



ECUSTEC Recruitment



ECUSTEC Projected and Actual Recruitment of Sites and Participants



ECUSTEC Screening Data



Trust Name	Site Name	Date of Full Approval	Number of patients identified/ approached	Total number of patients recruited
Alder Hey Children's NHS Foundation Trust	Alder Hey Children's Hospital			
Birmingham Women's and Children's NHS Foundation Trust	Birmingham Children's Hospital			
University Hospitals Bristol NHS Foundation Trust	Bristol Royal Hospital for Children	02/08/2017	7	2
Guy's and St Thomas' NHS Foundation Trust	Evelina London Children's Hospital	19/02/2018		
The Newcastle upon Tyne Hospitals NHS Foundation Trust	Great North Children's Hospital	10/07/2017	4	2
Great Ormond Street Hospital for Children NHS Foundation Trust	Great Ormond Street Hospital	10/08/2017	3	2
The Leeds Teaching Hospitals NHS Trust	Leeds General Infirmary	31/08/2017	1	0
Nottingham University Hospitals NHS Trust	Nottingham Children's Hospital	21/08/2017	3	0
NHS Greater Glasgow and Clyde	Royal Hospital for Children, Glasgow	06/09/2017	2	1
Central Manchester University Hospitals NHS Foundation Trust	Royal Manchester Children's Hospital	05/01/2018	0	0
University Hospital Southampton NHS Foundation Trust	Southampton Children's Hospital	30/11/2017	1	0
Cardiff and Vale University Health Board	University Hospital of Wales	25/01/2018	1	0



ECUSTEC Screening Data



- ECUSTEC Screening data is cross-referenced against public health data
 - ❖ Public Health England (PHE)
 - ❖ NHS National Services Scotland (NNS)
 - ❖ Public Health Wales (PHW)
- Nearly all cases of STEC HUS are being captured by ECUSTEC via screening logs and participating sites
- Reported back to NIHR EME
- Allowed recruitment barriers to be identified early on



ECUSTEC Site Visits



- ❑ ECUSTEC Trials Team visited the first 3 sites to recruit

Thank you for arranging with the Trials Team!

- ❑ Further site visits can be arranged for new sites
- ❑ Following an initial visit, only triggered visits will occur
- ❑ Trials team will require access to the Site File, CRFs and the patient medical notes



ECUSTEC Site Visit Outcomes



- No issues identified with protocol compliance
- Trial related activities i.e. consent discussions were well documented in the patient notes
- No unreported SAEs and potential SUSARs
- No identified unblinding had taken place



Reminders:

- Ensure all discussions are documented and in the correct order
- Ensure 'willingness to continue' is documented at each assessment visit and prior to any trial-related activities take place
- Ensure all of the eligibility criteria is documented in the patient notes



ECUSTEC Site Visit Outcomes



Reminders continued:

- Store a copy/document when the GP letters are sent
- Ensure Site File and Pharmacy File have the most recent signed delegation log, CVs and GCP certificates
- Document the version numbers of PIS, consent forms etc given to the patient/families
- Document the ECUSTEC Patient Trial Number in the patient notes





Thank You!

