Empirical oral AntibioticS for possible UTI in well-appearing Young febrile infants (EASY)

EASY R&D: A096909
IRAS: 1008782
Protocol number: 23012TW-CH
Target: 1.5 per month
Site number: 21
Proposed end of study: 30/10/2026

Eligibility

Inclusion Criteria

1. 29 to 90 days of age (Infants from their 29th day of life to their 90th day of life inclusive. Day of birth is day 1 of life)
2. Suspected urinary tract infection (UTI) requiring treatment with antibiotics
3. History of fever as defined as temperature ≥38°C measured by any method OR likely fever in last 24 hours including subjective fever reported by caregiver
4. Abnormal urinalysis defined as: (1) abnormal urinary dipstick test (leucocyte esterase ≥1+, or nitrite ≥Trace) OR (2) abnormal urine microscopy (≥5 white cells per high-power field in centrifuged urine or ≥10 white cells per mm3 in un-centrifuged urine or bacteriuria with any bacteria per high power field)
5. Well on global clinical assessment using the paediatric assessment triangle assessed by a consultant grade doctor*

Exclusion Criteria

1. Born at <30 weeks gestation
2. Discharged from hospital more than 7 days after birth
3. Required re-admission to hospital after birth for more than 24 hours
4. Known or suspected structural renal abnormality
5. Evidence of sepsis and/or meningitis (appear unwell, shock, hypotension, altered mental state, bulging fontanelle, lumbar puncture suggestive of bacterial meningitis)
6. Received vaccination within 48 hours of attendance
7. Sodium < 128mmol/l on lab or blood gas sample
8. Potassium > 6.5 mmol/l on lab sample
9. Plasma creatinine > 50 micromol/l
10. Inability to tolerate oral medication
11. Urine sample was not sent for culture
12. Received additional antibiotics (with the exception of the parenteral antibiotic administered within 24 hours of hospital attendance)
13. Declined consent for participation

*Please note that only a consultant-grade doctor can determine if a baby is well enough (point 5 of inclusion criteria). This can be any Emergency Medicine (EM) or Paediatric Consultant, and the consultant is not required to be on the delegation log.

Training requirements

For doctors confirming eligibility

- Protocol training (cascaded at site)
- Sign the delegation log and training forms
- GCP
- Signed and dated CV

Doctors must not perform any study-related activity until you have had the required training and been signed off by the PI on the training and delegation logs

Doctors completing early (24 & 36/48 hour) follow-up reviews

- Protocol training & SIV slides (cascaded at site)
- Sign training forms

General training and awareness

- Paediatric and ED clinicians will be made aware of the trial and the potential to start oral antibiotics. Multimodal awareness strategies will be used to achieve this.
- The ED Research Nurses will be joining the morning handover if a potential patient has been identified. Handover is at 08:30 - porta cabin near S block/concourse food hall.

Randomisation

Children may be randomised in the ED or on the wards if within 24 hours of hospital attendance and prior to the second dose of antibiotics. Administration of initial intravenous antibiotics does not exclude patients from being randomised to enter the study.

Screening

- The next sequential screening number will be found on the Excel Spreadsheet in SharePoint – EASY Screening Log v2.0.xlsx (sharepoint.com)

Randomisation

- Online web-based randomisation via CHaRT accessible at https://w3.abdn.ac.uk/hsru/EASY
- The format of the Participant Study Number is R21XXX. R for Randomisation, The first 2 digits (21) after 'R' are for the site number.
- 1st: R21001
- Document allocation in the notes using the SmartPhrase .EASYRANDOMISATION

Post randomisation

- Collect completed questionnaire – Drs please place this in the post box behind reception
- Only enter **eligible** patients into the MACRO database. This will be done by the ED Research Nurse Team

Study documents

Patient-facing documents

- The Patient Information Sheet (PIS) V 1.0 Final_13/10/2023 offers the following phone number to parents: **Paediatric Registrar on call – 07547 105930**
- Consent form Version 1.0 Final -13/10/2023

Clear folders

- Given to parent – contains questionnaires to be completed at 36 hours and on day 7 & 28 – **record screening number & study number on the pack and questionnaire envelopes**
- Spare questionnaire on consent – for parents declining – record screening number

Infographics

- Infographics used to support local clinicians and nursing are only for local awareness and training.
- Local infographics must not be shown to patients.

Investigator Site File

- Electronic and paper ISF – can use either

Follow-up

Eligible well-appearing infants may be discharged soon after clinician review regardless of whether they are in the oral or intravenous antibiotic groups.

If any clinical concerns are noted during the telephone follow-up, they should be escalated to the Paediatric Consultant of the Week (COW) or the Paediatric Registrar on call (details are on rotawatch).

Doctor follow-up

- Within 24 hours of randomisation – complete checklist and participant review (SmartPhrase .EASYREVIEW)
- 36/48 hour follow-up - complete checklist and participant review (SmartPhrase .EASYREVIEW)

Ongoing research team follow-up

- 24 hours data entry into MACRO
- 36/48 hours to complete the questionnaire on consent and send to CTU
- 36/48 hours to report an adverse events (AE)
- 7-day follow-up
  - RN – Complete checklist and participant review (SmartPhrase .EASYREVIEW)
  - RN - Peds QL infant + PedsQL Family Impact (parents to post to CTU)
- Day 28 follow-up
  - RN Checklist and Health Resource use and Activities questionnaire (enter onto MACRO)
  - Parents to post PedsQL Infant questionnaire to CTU
  - AEs, additional culture results, IP/OP appointments

Adverse events

AEs must be documented from time of consent until day 28.

- Laboratory-confirmed invasive bacterial infections (IBI), including bacterial meningitis and symptomatic bacteraemia, should be reported as AEs.
- Complications of peripheral venous access such as extravasation injury, tissued lines and line infections should be reported as AEs.
- All other events should be reported, including the new onset of vomiting, diarrhoea, rashes, or oral thrush (or a change in severity or frequency of these), which are common side effects of parenteral and oral antibiotics.

Contact details

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