# Randomised Empirical Antibiotic Duration in Intensive Care Unit

Submission date 21/08/2009	<b>Recruitment status</b> No longer recruiting	
<b>Registration date</b> 26/08/2009	<b>Overall study status</b> Completed	
Last Edited 07/06/2016	<b>Condition category</b> Infections and Infestations	

[X] Prospectively registered

[] Protocol

[] Statistical analysis plan

[X] Results

Individual participant data

### Plain English summary of protocol

Background and study aims

There are major concerns that the intensive care unit (ICU) is one of the main sources of hospital acquired infections in the NHS. Healthcare-acquired infections are a major cause of hospital complications and deaths. For many patients in the ICU, doctors may suspect that they have an infection on the basis of their clinical judgement. They then are put on a course of treatment with antibiotics for much of their stay. Recent studies are suggesting that prolonged antibiotics treatment in the absence of confirmed positive identification of infecting organisms is counterproductive and instead may cause more harm to the patient. The aim of this study is to investigate whether a reduced course of antibiotics is feasible and safe compared to the usual prolonged antibiotic treatment for ICU infections.

Who can participate? Patients at least 18 years of age in the ICU and suspected of having an infection.

What does the study involve?

Participants are randomly allocated to receive either seven days or two days of antibiotic treatment. We assess whether a reduced course of antibiotics is safe and as effective at preventing infections, and whether these reduced courses of antibiotics have any effect upon survival and length of stay in the ICU and hospital. We also assess whether a larger study is justified in order to address the cost to the NHS if the reduced antibiotics strategy is adopted.

What are the possible benefits and risks of participating? Not provided at time of registration

Where is the study run from? Liverpool Heart and Chest Hospital NHS Trust (UK)

When is the study starting and how long is it expected to run for? November 2009 to April 2011

Who is funding the study? Health Technology Assessment Programme (UK) Who is the main contact? Dr Nigel Scawn

### **Contact information**

**Type(s)** Scientific

**Contact name** Dr Nigel Scawn

**Contact details** Liverpool Heart and Chest Hospital NHS Trust Thomas Drive Liverpool United Kingdom L14 3PE

# Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

**Secondary identifying numbers** HTA 08/13/38; Protocol version 2.3

# Study information

### Scientific Title

A pilot randomised controlled trial comparing seven days versus two days of empirical antibiotics to treat hospital acquired infection of unknown origin in intensive care patients

### Acronym

READ-ICU

### Study objectives

We hypothesise that reduced duration of empirical antibiotics use in the intensive care unit (ICU) setting is likely to have the following impact on patients and the healthcare service:

1. Reduce overall ICU treatment costs

2. Reduce the risk of patients developing antibiotics resistant organisms e.g. methicillin-resistant Staphylococcus aureus (MRSA)

3. Reduce the risk of patients acquiring other infections e.g. Clostridium difficile

4. Reduce exposure of patients to unnecessary treatment likely to increase risk of allergic reactions

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/081338 Protocol can be found at: http://www.nets.nihr.ac.uk/\_\_data/assets/pdf\_file/0005/52196/PRO-08-13-38.pdf

Ethics approval required

Old ethics approval format

**Ethics approval(s)** To be submitted to the Liverpool Adult Research Ethics Committee - pending as of 21/08/2009

**Study design** Pilot single-centre randomised prospective study

**Primary study design** Interventional

**Secondary study design** Randomised controlled trial

**Study setting(s)** Hospital

**Study type(s)** Treatment

### Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied Healthcare-associated infections/sepsis

**Interventions** Seven days versus two days of empirical antibiotics.

Intervention Type Drug

**Phase** Not Applicable

#### Primary outcome measure

The rate of death or initiation of antibiotic therapy after the completion of the treatment schedule allocated at randomisation.

All outcome measures will be assessed at day 10 or at hospital discharge, whichever is sooner.

### Secondary outcome measures

- 1. Clinical
- 1.1. Duration of ICU stay
- 1.2. Duration of Hospital stay
- 1.3. Duration of mechanical ventilation
- 1.4. Incidence of infection with clostridium difficile
- 1.5. Incidence of infection with MRSA
- 2. Economic
- 2.1. Resource utilisation and costs
- 3. Feasibility outcomes
- 3.1. The ratio of patients screened : eligible : randomised
- 3.2. The incidence of cross-over between the randomised treatment groups
- 3.3. The accuracy of data collection assessed by a 20% source data verification check

All outcome measures will be assessed at day 10 or at hospital discharge, whichever is sooner.

### Overall study start date

01/11/2009

### **Completion date**

30/04/2011

# Eligibility

### Key inclusion criteria

Patients in the intensive care unit suspected of having infection of unknown origin will be eligible for inclusion if they are:

1. Both males and females, at least 18 years of age

2. Assent given by relatives/legal representative and written consent reaffirmed once the patient gets better. If patient is able to give informed consent this has to be given in writing.

### Participant type(s)

Patient

**Age group** Adult

## Lower age limit

18 Years

**Sex** Both

**Target number of participants** 60

### Key exclusion criteria

1. Positive blood cultures pre-randomisation

2. Patients currently enrolled in any other study where involvement in this pilot study would risk

deviation from either protocols 3. Allergy to treatment antibiotics

Date of first enrolment 01/11/2009

Date of final enrolment 30/04/2011

### Locations

**Countries of recruitment** England

United Kingdom

**Study participating centre Liverpool Heart and Chest Hospital NHS Trust** Liverpool United Kingdom L14 3PE

### Sponsor information

**Organisation** Liverpool Heart and Chest Hospital NHS Trust (UK)

Sponsor details Thomas Drive Liverpool England United Kingdom L14 3PE +44 151 2281616 bashir.matata@lhch.nhs.uk

**Sponsor type** Hospital/treatment centre

Website http://www.lhch.nhs.uk

ROR https://ror.org/01je02926

# Funder(s)

**Funder type** Government

**Funder Name** Health Technology Assessment Programme

Alternative Name(s) NIHR Health Technology Assessment Programme, HTA

**Funding Body Type** Government organisation

Funding Body Subtype National government

**Location** United Kingdom

### **Results and Publications**

#### **Publication and dissemination plan** Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2012		Yes	No