ISRCTN82694288 https://doi.org/10.1186/ISRCTN82694288

# Randomised Empirical Antibiotic Duration in Intensive Care Unit

**Submission date**
21/08/2009

**Recruitment status**
No longer recruiting

**Registration date**
26/08/2009

**Overall study status**
Completed

**Last Edited**
07/06/2016

**Condition category**
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
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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
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England
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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 |