

Randomised Empirical Antibiotic Duration in Intensive Care Unit

Submission date 21/08/2009	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 26/08/2009	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 07/06/2016	Condition category Infections and Infestations	☐ 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

Protocol serial number
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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s))**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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

England

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)

ROR

<https://ror.org/01je02926>

Funder(s)

Funder type

Government

Funder Name

Health Technology Assessment Programme

Alternative Name(s)

NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

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