ISRCTN13493757 https://doi.org/10.1186/ISRCTN13493757

A study of multidrug resistant organisms in the adult intensive care unit at Addenbrooke's Hospital

Submission date
13/02/2020

Recruitment status
No longer recruiting

Registration date
20/02/2020

Overall study status
Completed

Last Edited
06/03/2020

Condition category
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Healthcare-associated infections (HCAI) affect up to 10% of hospital patients, and are associated with an increased risk of death. Multidrug-resistant organisms (MDRO) are more common in hospitals. Patients in intensive care units (ICU) are particularly vulnerable to HCAI, and several outbreaks of infection with MDRO have been reported.

Current practices for screening for MDRO vary between countries, hospitals and units, reflecting a lack of information, and uncertainty about best practice. One strategy to reduce HCAI in ICUs would be to perform screening to look for MDRO in patients admitted to ICUs. This would enable earlier identification and treatment of MDRO and implementation of appropriate infection control measures to prevent their spread.

Whole-genome sequencing (WGS) is novel technology, which is more discriminatory than currently available typing methods. We are conducting a study to determine the rates of carriage, infection, and transmission of MDRO in the adult ICU at Addenbrooke’s Hospital, using WGS. This study will facilitate translation of this technology from a research tool into day-to-day clinical practice. Information from this study will be used to inform infection control and public health policies and procedures.

Who can participate?
Any adult admitted to the John Farman Intensive Care Unit during the study period.

What does the study involve?
All patients admitted to ICU during the study period will be screened for MDRO and clinical data on infections and antimicrobial use will be collected.

What are the possible benefits and risks of participating?
No direct benefits for study participation. In terms of the risks of participation in the study,

these are negligible as the study is observational in nature and there are no study-specific interventions or treatments. All specimens will be collected by experienced nursing staff, in accordance with routine clinical practice.

Where is the study run from?
Cambridge Biomedical Campus (UK)

When is the study starting and how long is it expected to run for?
June 2016 to December 2016

Who is funding the study?
1. Academy of Medical Sciences (UK)
2. The Health Foundation (UK)
3. National Institutes of Health Research Cambridge Biomedical Research Centre (UK)

Who is the main contact?
Dr Estee Torok
et317@cam.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Estee Torok

ORCID ID
http://orcid.org/0000-0001-9098-8590

Contact details
University of Cambridge, Department of Medicine, Box 157, Addenbrooke's Hospital, Hills Road, Cambridge
United Kingdom
CB1 7TP
01223 336845
et317@cam.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
180415

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

CUH R&D ref: A093680, IRAS 180415

Study information

Scientific Title
Whole-genome sequencing to investigate colonisation and transmission of multidrug-resistant organisms in the adult intensive care unit at Addenbrooke's Hospital

Acronym
ICU001

Study objectives
What is the prevalence of the colonisation and is there evidence of transmission of multidrug-resistant organisms in the adult intensive care unit?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/04/2016, NHS Health Research Authority, East of England - Cambridge Central Research Ethics Committee (Royal Standard Place, Nottingham NG1 6FS, UK; +44 (0)207 104 8388; NRESCommittee.EastofEngland-CambridgeCentral@nhs.net), ref: 15/EE/0318

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Screening

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
Surveillance for multidrug-resistant organisms

Interventions
All patients admitted to ICU during the study period will be screened for MDRO and clinical data on infections and antimicrobial use will be collected.

Participants will be screened for MDRO on admission to the John Farman Intensive Care Unit. All specimens will be assigned a unique anonymised identification number prior to transfer to the research laboratory the Department of Medicine for processing.

Participants will be screened for MDRO on discharge from ICU, and weekly during their ICU admission if the duration of admission is 7 days or longer.

Intervention Type
Other

Primary outcome measure
Measured using patient records during the study period:
1. Number of patients colonised with multidrug-resistant organisms
2. Number of patients with clinical evidence of infection with multidrug-resistant organisms
3. Number of transmission events of multidrug-resistant organisms

Secondary outcome measures
Measured using patient records during the study period:
1. Risk factors for colonisation / infection with multidrug-resistant organisms
2. Outcome of patients colonised / infected with multidrug-resistant organisms
3. Cost-consequences of whole-genome sequencing versus standard epidemiological investigation / typing for surveillance and investigation of suspected outbreaks and the management of confirmed outbreaks

Overall study start date
01/01/2016

Completion date
30/06/2017

Eligibility

Key inclusion criteria
1. Aged 18 years old or older
2. Male or female
3. Admitted to the John Farman Intensive Care Unit during the study period

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

All patients admitted to ICU in a 6 month period (N=400)

Key exclusion criteria
Does not fulfil study inclusion criteria

Date of first enrolment
20/06/2016

Date of final enrolment
20/12/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Cambridge Biomedical Campus
Cambridge University Hospitals NHS Foundation Trust
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust

Sponsor details
R&D Department
Cambridge University Hospitals NHS Foundation Trust
Hills Road
Cambridge
England
United Kingdom
CB2 0QQ
+44 (0)1223 348490
research@addenbrookes.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.cuh.org.uk/

ROR
https://ror.org/04v54gj93

Organisation
University of Cambridge

Sponsor details
School of Clinical Medicine
Box 111 Addenbrooke's Hospital
Hills Road
Cambridge
England
United Kingdom
CB2 0QQ
+44 (0)1223 766362
jo.deckers@admin.cam.ac.uk

Sponsor type
University/education

Website
http://www.cam.ac.uk/

ROR
https://ror.org/013meh722

Funder(s)

Funder type
Research organisation

Funder Name
Academy of Medical Sciences

Alternative Name(s)
The Academy of Medical Sciences

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Funder Name
The Health Foundation

Funder Name
National Institutes of Health Research Cambridge Biomedical Research Centre

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/12/2020

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version v2.0		06/03/2020	No	No
HRA research summary			28/06/2023	No	No