ISRCTN11601053 https://doi.org/10.1186/ISRCTN11601053

Tracking anti-microbial resistance across care settings in Liverpool (TRACS- Liverpool) - Part 1

Submission date
09/12/2021

Recruitment status
No longer recruiting

Registration date
17/12/2021

Overall study status
Completed

Last Edited
30/03/2022

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
This mixed methods study is the first stage of a programme of research looking at how antimicrobial resistance is acquired and transmitted within care settings in Liverpool. Antimicrobial resistance (AMR) threatens the effectiveness of antibiotics that are widely used in modern medicine. Some resistant bacteria pose a particular threat, namely a group called Enterobacterales. These bacteria become resistant to antimicrobials when they acquire genes that enable the bacteria to produce enzymes that destroy antibiotics. People frequently carry these resistant bacteria without knowing. But in some cases they cause illness that can be life threatening or untreatable.
Although we understand how people can acquire these bacteria – either through direct exposure, such as swallowing them, or through exposure to antibiotics; it is less clear when and how these resistant bacteria are transmitted.
We know that people requiring frequent hospital admissions, or who live in long term care facilities are at particular risk of acquiring resistant bacteria.
We also know that rates of antimicrobial resistance are higher in the north-west than in the rest of the UK.
In order to be able to accurately plan and explore the problem of antimicrobial resistance locally we first need to understand it.

Who can participate?
Health professionals working in institutions that operate in Merseyside with knowledge and experience relevant to the research questions.

What does the study involve?
We will interview up to 50 key informants from local health and care organisations in order to gain a deeper understanding of how the hospital and care systems work locally. These participants will be identified by their key roles within health and care settings across Liverpool and will be invited to take part accordingly.
We will compare this information with specific datasets about antimicrobial resistant infection rates from selected local hospitals.

Combining these different sources of information will allow us to identify how and where potential transmission may be occurring. We can then accurately plan how to explore this further in the next stage of the research.

What are the possible benefits and risks of participating?
None

Where is the study run from?
Liverpool School of Tropical Medicine (UK)

When is the study starting and how long is it expected to run for?
October 2021 to September 2022

Who is funding the study?
UKRI Strength in Places Fund (UK)
Unilever (UK)

Who is the main contact?
Maria Moore, maria.moore@lstmed.ac.uk

Contact information

Type(s)
Public

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
309060

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Sponsor 21-089, IRAS 309060, CPMS 51757

Study information

Scientific Title
Tracking anti-microbial resistance across care settings in Liverpool (TRACS-Liverpool) Part 1: informing the design and development of an observational cohort study

Acronym
TRACS - Liverpool: Part 1

Study objectives
Rationale for the study:
1. To inform the development of survey questions for a future longitudinal cohort study.
2. To inform the development of the sampling and recruitment strategies for the longitudinal cohort study.
3. To estimate rates of ESBL-E/CPE acquisition and infection in two Liverpool acute hospitals to inform sample size calculations.
4. To scope and document relevant routine and secondary data sources on local ESBL-E/CPE transmission
5. To document key informants' perspectives on the acceptability of the Part 2 study and how to improve it.
6. To map facility infrastructure, describe patient journeys within and between care facilities, and suggest how these might affect ESBL-E/CPE acquisition and prevention.
7. To review and summarise infection control policies for ESBL and CPE and suggest how these might be linked to protection from or acquisition of ESBL/CPE

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 16/02/2022, North West - Greater Manchester South Research Ethics Committee (3rd Floor, Barlow House, 4 Minshull Street, Manchester, M1 3DZ; +44(0)207 104 8143; gmsouthrec@hra.nhs.uk), ref:22/NW/0032

Study design
Observational cohort study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Infection control

Interventions
Following enrolment participants will undertake a single semi-structured interview with the research team. This may be online or face-to-face. This will complete their involvement in the study.

Intervention Type
Other

Primary outcome(s)
1.1. Estimate rates of ESBL-E/CPE acquisition and infection in two Liverpool acute hospitals, using readily available routine data sources at a single time point
Measured using interviews at a single time point:
2.1. Scope and document relevant routine and secondary data sources on local ESBL-E/CPE transmission.
2.2. Document key informants' perspectives on the acceptability of the Part 2 study and how to improve it.
2.3. Map facility infrastructure, describe patient journeys within and between care facilities, and suggest how these might affect ESBL-E/CPE acquisition and prevention.
2.4. Review and summarise infection control policies for ESBL and CPE and suggest how these might be linked to protection from or acquisition of ESBL/CPE

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
30/09/2022

Eligibility

Key inclusion criteria

1. Male or female aged 18 years or above
2. Health professionals working in institutions that operate in Merseyside
3. Having knowledge and/or experience to share on the research questions
4. Able to facilitate access to relevant data required in the study
5. Willing and able to give informed consent for participation in the study

Participant type(s)
Health professional

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Not willing or available to participate in the study

Date of first enrolment
01/02/2022

Date of final enrolment
30/04/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Liverpool Hospital
Liverpool University Hospitals Foundation NHS Trust
Prescot Street
Liverpool
United Kingdom
L7 8XP

Study participating centre

NHS Liverpool CCG
2 Renshaw Street
Liverpool
United Kingdom
L1 2SA

Sponsor information

Organisation
Liverpool School of Tropical Medicine

ROR
https://ror.org/03svjbs84

Funder(s)

Funder type
Government

Funder Name
UK Research and Innovation

Alternative Name(s)
UKRI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Unilever

Alternative Name(s)
Unilever Global, Unilever PLC, U

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Data sharing statement to be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			26/07/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes