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Evaluation of antibiotic use in coronavirus (COVID-19) hospitalised patients

Submission date
14/01/2021

Recruitment status
No longer recruiting

Registration date
17/05/2021

Overall study status
Completed

Last Edited
12/08/2025

Condition category
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Antibacterial agents (antibiotics) are usually used during the treatment of patients with more severe COVID-19 even though COVID-19 is caused by a virus, and antibiotics don't work against viruses. This is because doctors are concerned that there might be a bacterial infection on top of the viral infection, a so-called secondary infection, that is making matters worse. In fact, there is no good evidence to guide the use of antibiotics in COVID-19, and rates of secondary bacterial infection are thought to be low. The COVID-19 pandemic has therefore resulted in an unwanted increase in antibiotic use which will expose patients to more side effects, an increased risk of infection with superbugs, and increase costs.

This is a study about a blood test called procalcitonin (PCT) which is used in many hospitals to help diagnose bacterial infections and guide antibiotic treatment. There is a lack of clear evidence to support its use in lung infections, which means in some hospitals, clinicians have used the procalcitonin test to guide antibiotic decisions in COVID-19, whilst in other hospitals, they have not.

The PEACH study will analyse data from hospital trusts that did and did not use procalcitonin testing during the first wave of the COVID-19 pandemic. It will determine whether and how procalcitonin testing should be used in the NHS in future waves of COVID-19 to protect patients from antibiotic overuse.

Who can participate?
Patient-level data will be sourced from COVID-19 patients from 11 NHS acute hospitals

What does the study involve?
This study involves the analysis of data from before and during the first wave of the COVID-19 pandemic on the use of PCT testing by NHS trusts and hospitals from the antimicrobial pharmacist's network, professional networks of infection and critical care specialists, providers of PCT testing resources, Rx Info Ltd, Public Health England, and Public Health Wales. The study will also analyse the use of PCT testing and clinical outcomes of COVID-19 patients from 11 NHS acute hospitals during the first wave of the pandemic.

What are the possible benefits and risks of participating?
This study looks only at historical data so no benefits or risks are anticipated.

Where is the study run from?
The University of Leeds (UK)

When is the study starting and how long is it expected to run for?
From October 2020 to December 2022

Who is funding the study?
The National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Unfortunately, this study is not recruiting public volunteers at this time. This is because the research isn't ready for volunteers yet or the researchers are directly identifying volunteers in certain areas or hospitals. Please do not contact the research team as they will not be able to respond. For more information about COVID-19 research, visit the Be Part of Research homepage.

Study website
https://www.cardiff.ac.uk/centre-for-trials-research/research/studies-and-trials/view/peach

Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
v1.2

Study information

Scientific Title

PEACH: Evaluation of Antibiotic use in COVID-19 Hospitalised patients

Acronym
PEACH

Study objectives
The use of procalcitonin (PCT) testing, to guide antibiotic prescribing, safely reduced antibiotic use among patients who were hospitalised with COVID-19 during the first wave of the pandemic.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/03/21, West Midlands - Solihull Research Ethics Committee (The Old Chapel Royal Standard Place, Nottingham NG1 6FS; +44 (0)207 1048310; solihull.rec@hra.nhs.uk) Ref 21/WM /0052

Study design
Mixed methods controlled time-series analysis, matched case control study, interview study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
COVID-19 (SARS-CoV-2 infection), COVID-19 hospitalised patients

Interventions
PEACH will assess whether the use of procalcitonin (PCT) testing, to guide antibiotic prescribing, safely reduced antibiotic use among patients who were hospitalised with COVID-19 during the first wave of the pandemic in the UK.

This study will collect both trust-level and patient-level clinical data. Trust level data will be used to evaluate how widely PCT was used before the first COVID-19 wave, and the utilization of PCT testing to guide antibiotic prescribing during the first wave of COVID-19 pandemic in NHS hospital trusts caring for COVID-19 inpatients aged >16 years. Patient-level data will be used to evaluate the impact of PCT testing on antibiotic exposure and clinical outcome for COVID-19 patients.

Trust level data will be collected from different sources to maximise completeness and accuracy.
1. How widely PCT was used before and after the first wave of the COVID-19 pandemic in the UK using:
1.1. A questionnaire distributed to the antimicrobial pharmacist's network and through contacts within professional networks of infection and critical care specialists
1.2. Information from providers of testing resources
2.. Antibiotic consumption (Defined Daily Dose, by route and agent) between 01/03/2020 to 30 /06/2020 using data gathered by Rx Info Ltd, Public Health England, and Public Health Wales.

A retrospective observational analysis using propensity score matching will be used to assess the patient-level impact of PCT on antibiotic use and clinical outcomes. This analysis will use patient-level clinical data collected from 11 UK NHS trusts which did/did not use PCT routinely in COVID-19 patients aged >16 years. The patient-level cost of illness will be calculated from a secondary care NHS perspective from this data in a later stream of this study.

Semi-structured interviews with health care professionals will be used to explore the decision-making process around the use of antibiotics, identify the contextual factors, explore the feasibility and acceptability of PCT testing algorithms, and identify the key ingredients of successful implementation and normalisation of PCT algorithms in the management of COVID-19.

Intervention Type
Other

Primary outcome measure
Current primary outcome measure as of 13/09/2022:
1. Change in level and/or trend of antibiotic prescribing rates following the introduction of PCT testing. Measures using the weekly trend of the number of defined daily doses (DDDs) of prespecified antibiotics commonly used for respiratory tract infection ('CAP-DDD') per number of COVID+ admissions collected by Rx Info Ltd, Public Health England, and Public Health Wales between 01/03/2020 and 30/06/2022
2. Length of early antibiotics therapy measured using patient-level data collected within the first 7 days of admission
3. Patient-level cost of illness from COVID-19 in NHS trusts measured using data gathered by Rx Info Ltd, Public Health England, and Public Health Wales at baseline and during the first 7 days of admission
4. Identifying and reviewing published evidence of cost-effectiveness
5. Cost-effectiveness of different PCT testing strategies in COVID-19

Previous primary outcome measure:
1. Antibiotic prescribing rates following the introduction of procalcitonin (PCT) testing measured using the number of defined daily doses (DDDs) of prespecified antibiotics commonly used for respiratory tract infection (CAP-DDD) per number of COVID+ hospital admissions collected by Rx Info Ltd, Public Health England, and Public Health Wales between 01/03/2020 to 30/06/2020
2. Length of early antibiotics therapy measured using patient-level data collected within the first 7 days of admission
3. Patient-level cost of illness from COVID-19 in NHS trusts measured using data gathered by Rx Info Ltd, Public Health England, and Public Health Wales at baseline and during the first 7 days of admission

Secondary outcome measures

Current secondary outcome measures as of 13/09/2022:
1. Number of CAP-DDDs per total number of admissions collected by Rx Info Ltd, Public Health England, and Public Health Wales to calculate weekly trends between 01/03/2020 to 30/06/2020
2. Number of DDDs of all antibiotics (excluding anti TB) total DDDs (tDDDs) per number of COVID+ admissions collected by Rx Info Ltd, Public Health England, and Public Health Wales to calculate weekly trends between 01/03/2020 to 30/06/2020
3. Number of tDDDs per total number of admissions collected by Rx Info Ltd, Public Health England, and Public Health Wales to calculate weekly trends between 01/03/2020 to 30/06/2020
4. Number of CAP-DDDs per total number of patient bed days collected by Rx Info Ltd, Public Health England, and Public Health Wales to calculate weekly trends between 01/03/2020 to 30 /06/2020
5. Number of CAP-DDDs per number of COVID+ patient bed days collected by Rx Info Ltd, Public Health England, and Public Health Wales to calculate weekly trends between 01/03/2020 to 30 /06/2020
6. Number of tDDDs per total number of patient bed days collected by Rx Info Ltd, Public Health England, and Public Health Wales to calculate weekly trends between 01/03/2020 to 30/06/2020
7. Number of tDDDs per number of COVID+ patient bed days collected by Rx Info Ltd, Public Health England, and Public Health Wales to calculate weekly trends between 01/03/2020 to 30 /06/2020
8. Total length of antibiotic treatment measured using patient-level data collected at baseline and during the first 7 days of admission
9. tDDDs of antibiotics measured using patient-level data collected at baseline and during the first 7 days of admission
10. Duration of late antibiotic treatment measured using patient-level data collected at baseline and during the first 7 days of admission
11. DDDs of late antibiotic treatment measured using patient-level data collected at baseline and during the first 7 days of admission
12. DDDs of early antibiotic treatment measured using patient-level data collected at baseline and during the first 7 days of admission
13. Appropriateness of antibiotics according to local guidelines (% compliance) if practicable measured using patient-level data collected at baseline and during the first 7 days of admission
14. 30-day mortality measured using patient-level data collected at 30 days
15. 60-day mortality measured using patient-level data collected at 60 days
16. ICU admission measured using patient-level data collected at baseline and during the first 7 days of admission
17. ICU length of stay measured using patient-level data collected at ICU discharge
18. Length of hospital stay measured using patient-level data collected at discharge
19. Antimicrobial-resistant secondary bacterial infection measured using patient-level data collected at baseline and during the first 7 days of admission
20. Descriptive outcomes including types of antibiotic, route of administration and duration, frequency of PCT testing, and types of secondary bacterial infection measured using patient-level data collected at baseline and during the first 7 days of admission
21. Decision-making process around using antibiotics for patients with COVID measured using patient notes collected at baseline and during the first 7 days of admission
22. Feasibility, acceptability, and implementation of PCT testing algorithms in the management of COVID-19 measured using patient notes collected at baseline and during the first 7 days of admission

Previous secondary outcome measures:
1. Number of CAP-DDDs per total number of admissions collected by Rx Info Ltd, Public Health England, and Public Health Wales to calculate weekly trends between 01/03/2020 to 30/06/2020
2. Number of DDDs of all antibiotics (excluding anti TB) total DDDs (tDDDs) per number of

COVID+ admissions collected by Rx Info Ltd, Public Health England, and Public Health Wales to calculate weekly trends between 01/03/2020 to 30/06/2020
3. Number of tDDDs per total number of admissions collected by Rx Info Ltd, Public Health England, and Public Health Wales to calculate weekly trends between 01/03/2020 to 30/06/2020
4. Number of CAP-DDDs per total number of patient bed days collected by Rx Info Ltd, Public Health England, and Public Health Wales to calculate weekly trends between 01/03/2020 to 30 /06/2020
5. Number of CAP-DDDs per number of COVID+ patient bed days collected by Rx Info Ltd, Public Health England, and Public Health Wales to calculate weekly trends between 01/03/2020 to 30 /06/2020
6. Number of tDDDs per total number of patient bed days collected by Rx Info Ltd, Public Health England, and Public Health Wales to calculate weekly trends between 01/03/2020 to 30/06/2020
7. Number of tDDDs per number of COVID+ patient bed days collected by Rx Info Ltd, Public Health England, and Public Health Wales to calculate weekly trends between 01/03/2020 to 30 /06/2020
8. Total length of antibiotic treatment measured using patient-level data collected at baseline and during the first 7 days of admission
9. tDDDs of antibiotics measured using patient-level data collected at baseline and during the first 7 days of admission
10. Duration of late antibiotic treatment measured using patient-level data collected at baseline and during the first 7 days of admission
11. DDDs of late antibiotic treatment measured using patient-level data collected at baseline and during the first 7 days of admission
12. DDDs of early antibiotic treatment measured using patient-level data collected at baseline and during the first 7 days of admission
13. Appropriateness of antibiotics according to local guidelines (% compliance) if practicable measured using patient-level data collected at baseline and during the first 7 days of admission
14. 30-day mortality measured using patient-level data collected at 30 days
15. 60-day mortality measured using patient-level data collected at 60 days
16. ICU admission measured using patient-level data collected at baseline and during the first 7 days of admission
17. ICU length of stay measured using patient-level data collected at ICU discharge
18. Length of hospital stay measured using patient-level data collected at discharge
19. Acute kidney injury measured using patient-level data collected at baseline and during the first 7 days of admission
20 Antimicrobial-resistant secondary bacterial infection measured using patient-level data collected at baseline and during the first 7 days of admission
21. Descriptive outcomes including types of antibiotic, route of administration and duration, frequency of PCT testing, and types of secondary bacterial infection measured using patient-level data collected at baseline and during the first 7 days of admission
22. Decision-making process around using antibiotics for patients with COVID measured using patient notes collected at baseline and during the first 7 days of admission
23. Feasibility, acceptability, and implementation of PCT testing algorithms in the management of COVID-19 measured using patient notes collected at baseline and during the first 7 days of admission

Overall study start date
01/10/2020

Completion date
31/12/2022

Eligibility

Key inclusion criteria
Trust-level clinical data:
1. NHS hospital trust caring for COVID-19 inpatients aged >16 years

Patient-level clinical data:
1. Confirmed COVID-19 infection
2. Admitted to participating trust for any reason

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Patient-level data will be sourced from ~7000 COVID-19 patients from 11 NHS acute hospitals

Total final enrolment
6132

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/03/2020

Date of final enrolment
30/06/2020

Locations

Countries of recruitment
England

United Kingdom

Wales

Study participating centre
Leeds Teaching Hospitals NHS Trust
Beckett Street

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LS9 7TF

Study participating centre
Royal Liverpool University Hospital
Prescot Street
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Sponsor type
University/education

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

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan
Research findings will be disseminated through publications and reports submitted via a variety of audiences, such as NICE, Public Health England, Public Health Wales, British Society of Antimicrobial Chemotherapy (global antibiotic charity), and the British Infection Association.

Intention to publish date
31/03/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Cardiff Centre for Trials Research by contacting the study manager (Dr Joanne Euden) at PEACH@cardiff.ac.uk. Anonymised data will be provided upon production of the requestor's study protocol and agreement by Centre of Trials Research and study sponsor (Leeds University).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version v1.1	02/03/2021	17/05/2021	No	No
Results article	controlled interrupted time series analysis of organization-level data	08/02/2022	25/03/2022	Yes	No
Results article	retrospective observational study results	01/05/2021	25/03/2022	Yes	No
Protocol file	version 1.2	25/08/2022	13/09/2022	No	No
HRA research summary			28/06/2023	No	No
Results article	decision-making processes during the first wave of the COVID-19 pandemic	19/12/2023	08/01/2024	Yes	No
Results article	A retrospective propensity-score-matched cohort study of the impact of procalcitonin testing on antibiotic use in hospitalized patients during the first wave of COVID-19	09/09/2024	10/09/2024	Yes	No
Statistical Analysis Plan	version 1.0	07/09/2022	14/03/2025	No	No
Results article	Integrating the quantitative and qualitative data showed that PCT testing reduced antibiotic prescribing	08/08/2025	12/08/2025	Yes	No