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A study to determine which bacteria and viruses are detected in patients who develop pneumonia while in hospital

Submission date
09/02/2022

Recruitment status
No longer recruiting

Registration date
04/05/2022

Overall study status
Completed

Last Edited
07/06/2022

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
Hospital-Acquired Pneumonia (HAP) is a common and serious lung infection that occurs in all hospitals and on all wards. It particularly affects elderly patients. A new test called is available to help doctors decide which treatment to use for a patient with HAP. The test is called the BIOFIRE® FILMARRAY® PNEUMONIA PANEL - FAPP for short. The FAPP is approved for use in the EU and USA (CE marked and FDA approved). It detects the bacteria and viruses that cause HAP and genes that indicate resistance to certain antibiotics.
HAPOSS is a preliminary study aimed at describing how oftern different casues of HAP the FAPP would be detected if it were it were to be used in an NHS hospital.

Who can participate?
Adult patients (18 years or older) whose doctor wants to treat them for HAP.

What does the study involve?
HAPOSS involves using the FAPP to test a patient's sputum sample.

What are the benefits and risks of participating?
There are no direct benefits to patients who participate in HAPOSS however the results obtained will benefit future patients with HAP.
There are no risks associated with participation in HAPOSS.
FAPP can be used outside of a laboratory and requires only brief training and no prior laboratory experience. Results take 75 minutes, which is much quicker than standard microbiological tests.

Where is the study run from?
The study is run by a team who work at the University of Liverpool and the Liverpool University Hospitals NHS Foundation Trust (UK).

When is the study starting and how long is it expected to run for?
September 2018 to August 2022

Who is funding the study?
University of Liverpool (UK)

Who is the main contact?
Dr Dan Wootton, dwootton@liverpool.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Dan Wootton

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
268957

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
UoL001494, IRAS 268957, CPMS 44564

Study information

Scientific Title
Hospital Acquired Pneumonia Study of Sputum

Acronym
HAPOSS

Study objectives

The aim of HAPOSS is to describe the pattern of pathogen detections made by the bioFire Film Array Pneumonia Panel when used to sample a representative cohort of patients treated for non-ventilator acquired Hospital Acquired Pneumonia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/03/2020, East of England - Cambridge Central Research Ethics Committee (Royal Standard Place, Nottingham, NG1 6FS, UK; +44 2071048270; CambridgeCentral.rec@hra.nhs.uk), ref: 20/EE/0004

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Non ventilator acquired hospital acquired pneumonia

Interventions
The population of interest are patients who are about to be treated for non-ventilator acquired hospital acquired pneumonia (HAP).
At the descretion of the treating clinical team, sputum samples, obtained as part of standard clinical practice, are sub-sampled and tested using the bioFire FilmArray Pneumonia Panel.
The remaining sputum is sent for standard microbiological investigations which are reported in the usual way.
Results of the bioFire FilmArray Pneumonia Panel test are not revealed to the clinical team but are stored and analysed retrospectively.
Analysis will be descriptive and the results will be summary statistics such as frequency counts and proportions of individual pathogens detected, multiple pathogen detections and resistance genes detected.
The interpretation will be perfomed in the light of local and national treatment guidelines.

Intervention Type
Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)
bioFire FilmArray Pneumonia Panel

Primary outcome measure
Pneumonia pathogens are detected at baseline using the bioFire® FilmArray® Pneumonia Panel Plus

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
11/09/2018

Completion date
01/08/2022

Eligibility

Key inclusion criteria
Adults of 16 years or older who are treated as HAP within the two recruiting hospitals

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Intention is to palliate rather than cure
2. Non-English speaking
3. Patients from whom a sputum sample cannot be obtained within 6 hours of the administration

Date of first enrolment
01/08/2021

Date of final enrolment
01/08/2021

Locations

Countries of recruitment

England

United Kingdom

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

Sponsor information

Organisation
University of Liverpool

Sponsor details
Clinical Directorate
4th Floor Thompson Yates Building
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Liverpool
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United Kingdom
L69 3GB
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Sponsor type
University/education

Website
https://www.liverpool.ac.uk/

ROR
https://ror.org/04xs57h96

Funder(s)

Funder type
University/education

Funder Name

University of Liverpool

Alternative Name(s)
The University of Liverpool, , Universidad de Liverpool, UoL

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

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

Intention to publish date
01/12/2022

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will 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?
Participant information sheet	version 2	13/02/2020	15/02/2022	No	Yes
Protocol file	version 5	10/02/2020	15/02/2022	No	No
HRA research summary			28/06/2023	No	No