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A new device to examine raised level of proteins during inflammation

Submission date 08/02/2026	**Recruitment status** Not yet recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 12/02/2026	**Overall study status** Ongoing	
Last Edited 10/02/2026	**Condition category** Respiratory	

Plain English summary of protocol

Background and study aims

Sepsis is a major cause of illness and death worldwide. This is due to a dysregulated host immune response to infection and is associated with high levels of inflammatory molecules, which are also high in inflammatory conditions other than sepsis. There are diagnostic criteria based on clinical parameters or basic laboratory data (qSOFA, SARS) that can lack sensitivity and specificity. Biomarkers reflecting immune mechanisms underlying the host response to infection can add value in the diagnostic ability of the clinicians but often unavailable or may have a significant lag period between sample collection and processing. This makes it challenging to differentiate sepsis from infection without wider systemic inflammation. For example, there are conditions in the hospitalised patients (e.g. ventilator associated pneumonia) that can be difficult to diagnose due to varied clinical criteria and again lack of sensitivity and specificity and the fact that there can be bacterial colonisation in the respiratory system of these patients without causing systemic inflammation. The same is true in primary care, where it can be challenging for a clinician to diagnose bacterial or viral infection associated with impending systemic upset from patients who have an infection that will be contained with a balanced host response. Biomarkers can be helpful in this regard but are challenging to measure due to often high cost, lack of availability and prolonged turnaround time. Interleukin-6 (IL-6) has gained significant attention in sepsis diagnosis recently. This has also been a primary target of therapy during the COVID-19 pandemic. There needs to be development of easily performed biomarker assay that can be done close to the patients, making the results readily available to the clinician. The time taken for standard ELISA-based method for detection of biomarkers of inflammation is long, mostly because of the need for the laboratory transit and analysis time, and they are expensive. The immediate availability of assays at the bedside and at clinic can enhance clinicians' ability to diagnose sepsis and related condition in quick time and facilitate triage and early treatment, potentially resulting in reduced illness and death. In the area of global health, significant improvement have been achieved by similar assays being made available for other conditions with high incidence and high mortality burden (e.g. point of care testing for cardiac troponin). A smartphone-based microfluidic biochip has been proposed for detection of inflammatory markers within ICU. There has been previous work by one of the co-investigator's group developing an assay that can use a microfluidic assay for detection of inflammatory protein.

The purpose of this feasibility study is to examine the proposed assay in detecting elevated level

of IL-6 in patients admitted to hospital with suspected infection in the lungs, through a new method. This will aid in rapid diagnosis, and also help risk stratification for triaging for admission decisions and also assessing patients' eligibility for advanced therapies.

Who can participate?
Patients aged over 18 years admitted to the hospital with suspected lung infection (acute exacerbation of COPD, pneumonia, hospital or ventilator associated pneumonia), less than 72 hours within admission. This group of patients are known to have a wide range of raised IL-6 levels, which would be suitable for the objective of the current study.

What does the study involve?
The study involved using a small portion of the blood sample already taken for clinical analysis to be used by the proposed assay and also by ELISA for IL-6 measurement. This will therefore not involve a specific blood draw or venepuncture for the analysis. Following consent, a part of the withdrawn blood will be segregated in the laboratory and utilised in the study.

What are the possible benefits and risks of participating?
There is no direct benefit at the current time, other than contributing to development of medical science.
There aren't any identified risks, discomfort or inconvenience associated with the study. The data will be anonymised at source and data related risk will be minimised as a result.

Where is the study run from?
Medway NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
February 2026 to October 2026

Who is funding the study?
Royal Academy of Engineering (UK)

Who is the main contact?
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Contact information

Type(s)
Principal investigator, Public, Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
342215

Study information

Scientific Title
A feasibility study for microfluidic devices for inflammatory protein

Study objectives
To assess the feasibility of testing for IL-6 and validity of the results of the proposed assay against the gold standard (ELISA).

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 19/07/2024, Brighton and Sussex Research Ethics Committe, Health Research Authority (Health Research Authority, 2 Redman Place, London, E20 1JQ, United Kingdom; +44 (0)207104 8202; brightonandsussex.rec@hra.nhs.uk), ref: 24/LO/0346

Primary study design
Observational

Secondary study design
Cross sectional study

Study type(s)

Health condition(s) or problem(s) studied
Respiratory infection/inflammation

Interventions
Informed consent:
Informed consent will be obtained by the research practitioner (GCP trained) and Principal Investigator and members of the research team on the delegation log. The patients who fulfil the criteria will be approached by the research practitioners and the procedures will be explained verbally and with the Patient Information Sheet. The participant will be allowed as much time as wished to consider the information, and the opportunity to question the Investigator, their GP or other independent parties to decide whether they will participate in the study. Written Informed Consent will then be obtained by means of participant dated signature and dated signature of the person who presented and obtained the informed consent. A copy of the signed Informed Consent will be given to the participants. It will be clearly stated that the

participant is free to withdraw from the study at any time for any reason without prejudice to future care, and with no obligation to give the reason for withdrawal. When a patient cannot consent for themselves, a patient representative or a nominated consultee will be used.

Screening and eligibility assessment:
During the study period, all patients admitted to the ICU and respiratory ward will be screened for study eligibility by the routine clinical staff within the research team and will be approached for consent. Once consent has been obtained, the following routine blood sample taken for clinical reasons will be used for study assays. GCP certified research personnel familiar with the protocol and on the delegation log will be carrying out the consent and data collection. A designated trained laboratory practitioner will prepare the sample for further analysis.

Demographics:
Age, gender, race, smoking and drinking habits will be recorded.

Medical history:
Details of any history of disease or surgical interventions in the following systems will be recorded against the given code in the anonymized database by research members in the routine clinical team:

Concomitant medication:
All over-the-counter or prescription medication, vitamins, and/or herbal supplements will be recorded on CRFs against the given code in the anonymized database by research members in the routine clinical team.

Physical examination:
Usually obtained physiological variable close to the time of blood collection will be recorded (temperature, heart rate, blood pressure, respiratory rate, Glasgow Coma Scale) against the given code name in the anonymized database by research members in the routine clinical team

Laboratory tests:
Routinely obtained laboratory assays (full blood count, renal profile, liver profile, CRP) will be recorded.

Subsequent assessments:
No subsequent assessment will be done on participants other than examining concomitantly collected data for assessing divergence between the study assay and ELISA and for sharing the results with peers.

Definition of the end of trial:
The end of the trial will be at the end of all assays completion and analysing the results.

Discontinuation/withdrawal of participants from the study:
Each participant has the right to withdraw from the study at any time. Another potential reason for withdrawal will be any contamination or loss of quality of the samples under unavoidable circumstances.
The reason for withdrawal will be recorded in the CRF.

Source data:
Source documents are original documents, data, and records from which participants' CRF data are obtained. These include, but are not limited to, hospital records (from which medical history and previous and concurrent medication may be summarised into the CRF), clinical and office

charts, laboratory and pharmacy records, diaries, microfiches, radiographs, and correspondence. CRF entries will be considered source data if the CRF is the site of the original recording (e.g., there is no other written or electronic record of data).
All documents will be stored safely in password protected device with access only to research personnel. On all study-specific documents, other than the signed consent, the participant will be referred to by the study participant number/code, not by name.

Description of study interventions:
A microfluidic device fabricated for this study will be used to measure IL-6 level in serum.

The device will be coated using polymer that allows the binding of serum protein with the glass substrate. Later on, we plan to use the primary antibody to detect the protein of interest (IL-6) followed by washing. Next, we will use a fluorescent tagged secondary antibody (along with a wash) followed by imaging of fluorescent dots as shown in the schematic. The assay parameters including incubation time for serum, antibody binding, and washing time will be optimized with Il-6 spiked in artificial serum.
Imaging and analysis: We plan to image using a portable microscope and use a deep learning enabled software for automation of image processing. The above workflow has been used for detecting protein from serum [Unpublished data, patent under preparation]. Previously similar methods have been developed and shared by the device development group.5
The advantages of the proposed method,
1. Reduction in turnaround time
2. Microchambers lead to reduction in antibody consumption.
3. The device cost is lesser than the cost of ELISA plate reader.
4. The testing can be done for a single patient near bedside or in a facility close to the patient care area (does not require large number of patient samples)
5. The imaging system and the device is portable and can be kept bedside/home (in contrast to ELISA machine)

Maintenance of storage of study device:
As per usual laboratory protocol for biological and possibly infective samples

Intervention Type
Device

Phase
Phase I

Drug/device/biological/vaccine name(s)
Microfluidic device

Primary outcome(s)
1. Criterion validity of IL-6 level results generated through the microfluidic device, measured using quantitative versus semi-quantitative in the new assay, at aim for 30 days to collect sample, preserve samples and batch process in two phases (please refer to above start and completion dates of the study)

Key secondary outcome(s))

1. The timeframe for turnover, technical challenges in using the microfluidic device to measure IL-6 levels, measured using hours versus days, at aim for 30 days to collect sample, preserve samples and batch process in two phases (please refer to above start and completion dates of the study)

Completion date
31/10/2026

Eligibility

Key inclusion criteria
1. Participant is willing and able to give informed consent for participation in the study
2. Age >18 years
3. Admitted to the hospital with suspected lung infection (acute exacerbation of COPD, pneumonia, hospital or ventilator associated pneumonia)
4. Less than 72 hours within admission

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
90 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Potential sources of infection or inflammation outside lungs according to the treating clinician
2. Patients without the capacity to consent
3. Underlying malignancy

Date of first enrolment
23/02/2026

Date of final enrolment
30/09/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Medway NHS Foundation Trust
Medway Maritime Hospital
Windmill Road
Gillingham
England
ME7 5NY

Sponsor information

Organisation
Medway NHS Foundation Trust

ROR
https://ror.org/01apxt611

Funder(s)

Funder type

Funder Name
Royal Academy of Engineering

Alternative Name(s)
RAEngineering, RAEngNews, The Royal Academy of Engineering (RAEng), RAENG

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available