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Immune function of sepsis patients in intensive care and intermediate care units

Submission date
07/01/2026

Recruitment status
Recruiting

Registration date
15/01/2026

Overall study status
Ongoing

Last Edited
12/01/2026

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
Sepsis is a serious condition where the body's response to an infection becomes harmful and can lead to organ failure. People with sepsis can look very different from each other, and routine blood tests do not fully capture these differences. The immune system can be overactive in some patients and suppressed in others, and these patterns may change over time. This study aims to map how the immune system responds during sepsis by analysing blood samples collected at several time points. By combining immune measurements with clinical information, the study aims to identify patterns ("profiles") that are linked to illness severity and could support better patient stratification in the future.

Who can participate?
Adults (18 years or older) who are admitted to an intensive care unit (ICU) or an intermediate care unit and are treated for a suspected infection, with signs of organ dysfunction requiring organ support, may be invited to take part. A comparison group of infected ICU/intermediate care patients who do not meet Sepsis-3 criteria, and a group of healthy volunteers, may also participate.

What does the study involve?
Participants will have blood samples collected as early as possible after ICU/intermediate care admission (within 24 hours). For patients with suspected sepsis, additional blood samples will be collected later during the hospital stay (around day 3–4 and day 8–15) if the participant is still in hospital. Clinical information (such as vital signs, laboratory results, organ support, and outcomes during admission) will be collected from medical records. The blood samples will be analysed using advanced laboratory methods to measure immune cells, gene activity (RNA), and proteins in the blood.

What are the possible benefits and risks of participating?
There may be no direct medical benefit to participants, because the study tests are for research and are not intended to guide immediate clinical care. The main potential benefit is that the findings may improve understanding of sepsis and support better diagnostics and patient

stratification in the future. Risks are mainly related to blood sampling, such as temporary discomfort, bruising, bleeding, or rarely infection or dizziness. No experimental treatment is given as part of this study.

Where is the study run from?
The study is run from Karolinska University Hospital (Solna and Huddinge sites), Danderyds Hospital, and Södersjukhuset, in Stockholm, Sweden.

When is the study starting and how long is it expected to run for?
Inclusion of patients started in January 2023 and is expected to continue until December 2027.

Who is funding the study?
The study is funded by the Swedish Research Council, NordForsk, Centre for Innovative Medicine, and Region Stockholm (ALF Medicine).

Who is the main contact?
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Contact information

Type(s)
Principal investigator, Public, Scientific

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Additional identifiers

Study information

Scientific Title
Immune profiling of sepsis patients in intensive care and intermediate care units

Study objectives
The study is conducted to improve understanding of how the host immune response evolves in sepsis and how immune alterations relate to disease severity and clinical outcomes in critically ill patients. Using systems biology approaches (transcriptomics, high-dimensional proteomics, and high-dimensional flow cytometry) on longitudinal blood samples, the study aims to characterise

immune profiles in adult patients admitted to intensive care or intermediate care with suspected infection and organ dysfunction requiring organ support, and to compare these profiles with (i) infected ICU/intermediate care patients who do not fulfil Sepsis-3 criteria and (ii) healthy controls. By integrating detailed clinical data with immune, transcriptomic and proteomic profiles, the study seeks to identify sepsis-associated patient phenotypes with distinct marker-expression patterns and to explore candidate plasma biomarkers that may support risk stratification and precision diagnostics. Sex will be examined as a biological variable in uni- and multivariable analyses.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 22/03/2021, Ethics Review Authority, Umeå Department of Medicine (Etikprövningsmyndigheten, Umeå avdelning medicin) (Etikprövningsmyndigheten, Box 2110, Uppsala, 750 02, Sweden; +46 10 4750800; registrator@etikprovning.se), ref: 2020-06545

Primary study design
Observational

Secondary study design
Longitudinal study

Study type(s)

Health condition(s) or problem(s) studied
Suspected sepsis with organ dysfunction in adult patients admitted to intensive care or intermediate care units.

Interventions
This is a prospective observational cohort study conducted at Karolinska University Hospital (Solna and Huddinge), Danderyds Hospital, and Södersjukhuset, Stockholm, Sweden. Adult patients are enrolled on admission to an intensive care unit (ICU) or intermediate care unit and meet criteria for suspected sepsis, defined as suspected/probable infection treated with antimicrobial therapy in combination with at least one acute organ dysfunction requiring organ support (aligned with SOFA-related organ dysfunction). The first blood sample is collected within 24 hours of ICU/intermediate care admission. Longitudinal sampling is performed with follow-up samples around day 3–4 and day 8–15 if the participant remains hospitalised. Participants are classified into sepsis and non-sepsis groups based on whether Sepsis-3 criteria are fulfilled prior to the second sampling time point. Samples include EDTA plasma, PAXgene tubes for RNA, and whole blood for cellular analyses; healthy controls are sampled using corresponding procedures. Whole blood is stabilised/cryopreserved and analysed using multiparameter, high-dimensional flow cytometry with specific immune cell panels. Transcriptomic and proteomic analyses are performed on longitudinal samples. Data are quality-controlled and analysed using standardised workflows, including extraction of cell subset frequencies and marker expression, exploratory dimensionality reduction and clustering, and statistical analyses integrating clinical variables.

Intervention Type
Other

Primary outcome(s)
1. Sepsis at admission to ICU/intermediate care unit to hospital discharge/death measured using Sepsis-3, based on chart review, at one time point

2. Hospital mortality from admission to ICU/intermediate care unit to hospital discharge/death measured using chart review at one time point

Key secondary outcome(s))
1. Duration of hospital stay from admission to ICU/intermediate care unit to hospital discharge /death measured using chart review at one time point

2. Duration of stay in intensive care and/or intermediate care units, from admission to ICU /intermediate care unit to hospital discharge/death measured using chart review at one time point

Completion date
31/12/2032

Eligibility

Key inclusion criteria
1. Age: ≥18 years.
2. Setting: Admitted to an intensive care unit (ICU) or intermediate care unit (IMCU/intermediate care).
3. Condition: Suspected sepsis, defined as suspected/probable infection treated with antimicrobial therapy and at least one acute organ dysfunction requiring organ support.
4. Sampling feasibility: Ability to provide study blood samples according to protocol.
5. Consent: Informed consent to participate in the study.

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

Key exclusion criteria

1. Previously included in the same study.
2. Moribund patient.
3. Informed consent for participation not obtained.

Date of first enrolment
01/01/2023

Date of final enrolment
31/12/2027

Locations

Countries of recruitment
Sweden

Sponsor information

Organisation
Karolinska Institutet

ROR
https://ror.org/056d84691

Funder(s)

Funder type

Funder Name
Vetenskapsrådet

Alternative Name(s)
Swedish Research Council, VR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Sweden

Funder Name
NordForsk

Alternative Name(s)

Funding Body Type
Government organisation

Funding Body Subtype
Associations and societies (private and public)

Location
Norway

Funder Name
Center for Innovative Medicine

Alternative Name(s)
CIMED

Funding Body Type
Private sector organisation

Funding Body Subtype
Research institutes and centers

Location
Sweden

Funder Name
Region Stockholm

Results and Publications

Individual participant data (IPD) sharing plan

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 1.7	29/03/2023	12/01/2026	No	Yes