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The impact of initial scores, white blood cell and platelet counts, and albumin on length of stay and mortality in sepsis patients

Submission date
02/07/2023

Recruitment status
No longer recruiting

Registration date
13/07/2023

Overall study status
Completed

Last Edited
14/11/2023

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
Sepsis is the failure of the immune system to overcome the reaction to infection. Sepsis is a global problem. Simple clinical scores are used in the early detection of sepsis patients, but there are no satisfactory parameters in predicting patient outcomes, especially length of stay and in-hospital mortality. Early detection is a crucial part of its management. This study aims to provide a good parameter to predict the length of stay and in-hospital mortality in sepsis patients. These parameters are expected from clinical scores and laboratory examinations so that they can be used widely.

Who can participate?
Patients aged 18 - 80 years old were admitted from the emergency department to ICU and diagnosed with sepsis

What does the study involve?
This study uses medical record data from sepsis patients who were admitted to the ICU. Vital sign data (respiratory rate, pulse rate, blood pressure, temperature, oxygen saturation) will be extracted to predict patient outcomes (length of stay in the ICU and mortality). The data taker extracts these data from medical records manually. Then these data will be analysed by the investigator.

What are the possible benefits and risks of participating?
The results of this study are expected to provide information to clinicians (general practitioners and related specialists) based on simple clinical and laboratory scores regarding the degree of patient severity and its relationship to patient outcomes. More attention to patients with poor parameter results is expected to reduce the risk of morbidity and mortality in sepsis patients at UPI. The risk from the use of patient data is the leakage of patient information. However, this risk is mitigated by storing research data in special cabinets with certain locks. Access is only allowed by the principal investigator.

Where is the study run from?
Mohammad Soewandhie General Hospital Surabaya (Indonesia)

When is the study starting and how long is it expected to run for?
August 2022 to August 2023

Who is funding the study?
Universitas Ciputra Surabayaa (Indonesia)

Who is the main contact?
Erik Jaya Gunawan, erik.jaya@ciputra.ac.id (Indonesia)

Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Clinical scores, leucocyte differential counts, platelet counts, and albumin serum levels in emergency department predict the length of stay and in-hospital mortality in sepsis patient in the ICU

Study objectives
Higher clinical scores, higher neutrophil, lower lymphocyte, lower platelet, and lower albumin serum levels predict longer length of stay and higher in-hospital mortality in sepsis patients in the ICU

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 15/08/2022, Komite Etik Penelitian Kesehatan RSUD dr. Mohamad Soewandhie (Ethical Comittee in Health Research Mohommad Soewandhie General Hospital) (Jalan Tambak Rejo No. 45-47, Surabaya, 60142, Indonesia; + 62 (031) 3717141; rsud_soewandhie@surabaya.go.id), ref: 013/KE/KEPK/2022

Study design
Single-center observational cohort retrospective study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Sepsis

Interventions

This study looks at the impact of initial scores, white blood cell and platelet counts, and albumin on length of stay and mortality in sepsis patients. Sepsis is a global problem. Simple clinical scores are used in the early detection of sepsis patients, but there are no satisfactory parameters in predicting patient outcomes, especially length of stay and in-hospital mortality. These parameters are expected from clinical scores and laboratory examinations so that they can be used widely.

This is an observational study using medical record data. Vital sign data in the first 24 hours at the Emergency Department (ED) will be extracted to calculate the clinical score. Laboratory results at ED will be extracted. Length of stay in the ICU (days) will be counted from the first day of care in the ICU. In-hospital mortality was extracted from the death certificate in the medical record. All Data from patients who were admitted to the ICU from September 2021 to August 2022, aged 18-80 years old, diagnosed with sepsis will be extracted. The exclusion criteria include patients who survived in ICU < 24 hours, pregnancy, cancer, autoimmune disease, and COVID-19 disease. The dropout criteria are incomplete and duplicate data. Patient demographic data (sex, age, weight, source of infection, and comorbidities) extraction will be performed from September – November 2022 and analysed using descriptive statistical methods in SPSS Software. Each data collection session obtained 10-15 medical records. Data from independent and dependent variables are subjected to a bivariate test (using a different test according to the type of data). All independent variables which have significant differences are analyzed using multivariate analysis (using a logistic regression test). For significant variables, statistical analysis is continued using the ROC curve to determine the sensitivity and specificity values.

Management and recording of data are performed by the healthcare provider in charge. The healthcare provider included General Practitioner on duty and a nurse on duty in ED and ICU. Medical record data is extracted by the data taker. The data taker was a medical student who was trained to fill out the case report form. Extraction of medical record data was undertaken using a manual procedure (from medical record data to hand-written case report form) at the hospital medical record unit at Mohamad Soewandhie General Hospital Surabaya (medical record unit).

Intervention Type
Other

Primary outcome(s)
1. Length of Stay in ICU (days) measured using total days of care in the ICU from medical record data (admitted until discharged from ICU) at the time of data collection
2. In-hospital mortality measured using death certificates in the medical record data at the time of data collection.

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

Completion date
11/08/2023

Eligibility

Key inclusion criteria

1. Aged 18-80 years old
2. Patient admitted to the Emergency Department
3. Diagnosed with Sepsis

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
80 years

Sex
All

Total final enrolment
150

Key exclusion criteria
1. Did not survive > 24 hours after being admitted to ICU
2. Pregnancy or post partum
3. Cancer
4. Autoimmune disease
5. COVID-19 infection

Date of first enrolment
13/09/2022

Date of final enrolment
04/11/2022

Locations

Countries of recruitment
Indonesia

Study participating centre
Dr Mohammad Soewandhie General Hospital Surabaya
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Sponsor information

Organisation
Universitas Ciputra

ROR
https://ror.org/01zj4g759

Funder(s)

Funder type
University/education

Funder Name
Ciputra University

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Erik Jaya Gunawan, erik.jaya@ciputra.ac.id. These datasets will take the form of raw data in Excel and will be shared by email. Patient data will be identified only by using a participant ID number.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results			14/11/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file			13/07/2023	No	No