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Sepsis diagnosis transformed: artificial intelligence-clinical decision support system clinical impact

Submission date	**Recruitment status**	[X] Prospectively registered
25/07/2024	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
26/07/2024	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
25/07/2024	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims

Sepsis is a life-threatening response to infection that can lead to tissue damage, organ failure, and death if not recognized and treated promptly. According to the World Health Organization, sepsis was responsible for approximately 20% of global deaths in 2017, with 48.9 million cases and 11 million fatalities. The mortality rate for sepsis is high at 32.2%, increasing to 38.5% for those who develop septic shock. Sepsis primarily affects high-risk groups such as the elderly, ICU patients, and those with chronic conditions or compromised immune systems. The prevalence of sepsis, intensified by drug-resistant infections, underscores the need for more effective prevention, treatment methods, and rapid diagnostic strategies.

This study introduces an artificial intelligence-clinical decision support system (AI-CDSS) that uses machine learning algorithms to analyze blood test data (complete blood count with differential, or CBC + DIFF) to quickly assess the risk of sepsis. The aim of this study is to determine if the use of AI-CDSS reduces mortality rates among sepsis patients and lowers the rate of progression to septic shock and other complications, such as acute respiratory distress syndrome (ARDS), acute kidney injury (AKI), and multiple organ dysfunction syndrome (MODS), etc.

Who can participate?

Licensed healthcare professionals aged 18 years and over, including postgraduate year residents, residents, fellows, or attending physicians involved in diagnosing and managing sepsis, with at least one year of clinical experience.

What does the study involve?

Participants in this randomized controlled trial will be divided into two groups: an intervention group using the AI-CDSS for sepsis diagnosis and management, and a control group following standard practices. Participants will be randomly assigned to either group using a computer-generated sequence to ensure fairness and reduce bias. Both groups will be monitored and analyzed on days 7, 14, and after patient discharge to evaluate the impact of the diagnostic approach on clinical decision-making and patient outcomes. The study will measure treatment

initiation times, patient recovery rates, incidence of complications such as septic shock, and overall mortality rates.

What are the possible benefits and risks of participating?
Participants may benefit from using the AI-CDSS by making more accurate and timely decisions in sepsis management, potentially leading to better patient outcomes. There are no significant risks associated with participating in this study, as patient care will continue to be guided by clinical judgment and standards. The AI tool is intended to support, not replace, the professional decision-making process.

Where is the study run from?
The study is being conducted at Tri-Service General Hospital (Taiwan), which has agreed to implement and test this new technology.

When is the study starting and how long is it expected to run for?
June 2024 to January 2025

Who is funding the study?
Tri-Service General Hospital (Taiwan)

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, 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
Improving sepsis prognosis with artificial intelligence-clinical decision support system (AI-CDSS): clinical efficacy

Study objectives
Primary Hypothesis:
The use of the AI-CDSS for sepsis diagnosis and management enables healthcare professionals to treat patients earlier and more efficiently, thereby reducing mortality rates compared to those using standard diagnostic practices.

Secondary Hypothesis:
The implementation of AI-CDSS lowers the rate of progression to septic shock and other complications related to sepsis, such as acute respiratory distress syndrome (ARDS), acute kidney injury (AKI), multiple organ dysfunction syndrome (MODS), disseminated intravascular coagulation (DIC), liver failure, myocardial dysfunction, etc.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 17/06/2024, Institutional Review Board of Tri-Service General Hospital (No.325, Sec.2, Cheng-Kung Rd. Neihu, Taipei City, 114202, Taiwan; +886 87923311 ext 17763; tsghirb@ndmctsgh.edu.tw), ref: C202305073

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention, Efficacy

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

Interventions
This randomized controlled trial involves healthcare practitioners who will be divided into two groups: one using the AI-CDSS and the other following standard sepsis diagnostic practices. The intervention group will use the AI-CDSS, which integrates machine learning algorithms with complete blood count with differential (CBC + DIFF) data to assess the risk of sepsis in real-time, supporting clinical decision-making.

Participants are randomly assigned to either the intervention group (AI-CDSS assisted) or the control group (standard diagnostic practices) using a computer-generated sequence to ensure

blinding and reduce allocation bias. Both groups will be monitored and analyzed on days 7, 14, and after the patient is discharged, focusing on incidence of complications such as septic shock and overall mortality rates.

Intervention Type
Other

Primary outcome(s)
Mortality rates among patients assessed by tracking and analyzing patient outcomes on days 7, 14, and after discharge.

Key secondary outcome(s))
Severity and occurrence of complications measured by rate of progression to septic shock and the incidence of sepsis-related complications such as acute respiratory distress syndrome (ARDS), acute kidney injury (AKI), multiple organ dysfunction syndrome (MODS), disseminated intravascular coagulation (DIC), liver failure, myocardial dysfunction, etc. These complications will be tracked and analyzed on days 7, 14, and after discharge to assess the

Completion date
15/01/2025

Eligibility

Key inclusion criteria
1. Professional Status: Must be a licensed health professional authorized to diagnose and manage sepsis, including postgraduate year residents, residents, fellows, or attending physicians in relevant departments such as emergency medicine, intensive care, and infectious diseases.
2. Clinical Experience: Must have a minimum of one year of clinical experience, ensuring familiarity with sepsis diagnosis and management protocols.
3. Access to Technology: Must have regular access to the necessary technological infrastructure to use the AI-CDSS, including computers or tablets with internet connectivity. This infrastructure should also be integrated into the hospital’s electronic health record system where feasible.
4. Training Willingness: Must be willing to undergo a brief training session on the use of the AI-CDSS to ensure proper understanding and effective utilization of the system, focusing on how it integrates with sepsis diagnostic and management protocols.

Participant type(s)
Health professional

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Non-Diagnostic Roles: Health professionals who are not directly involved in diagnosing or managing patient care, such as administrative staff, nurses without diagnostic responsibilities, or medical students who do not participate in clinical decision-making.
2. Inexperience in Sepsis Management: Health professionals with less than one year of clinical experience in departments relevant to sepsis care, ensuring that all participants have adequate exposure to sepsis management practices.

Date of first enrolment
01/08/2024

Date of final enrolment
31/12/2024

Locations

Countries of recruitment
Taiwan

Study participating centre
Tri-Service General Hospital
No. 325, Sec. 2, Chenggong Rd., Neihu Dist.
Taipei City
Taiwan
114202

Sponsor information

Organisation
Tri-Service General Hospital

ROR
https://ror.org/007h4qe29

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Tri-Service General Hospital

Alternative Name(s)
Sānjun Zongyīyuàn, Tri-Service General Hospital, Taiwan, TSGH

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Taiwan

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			25/07/2024	No	Yes