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Effectiveness of an artificial intelligence clinical decision support system for early detection of sepsis

Submission date
09/07/2024

Recruitment status
No longer recruiting

Registration date
12/07/2024

Overall study status
Completed

Last Edited
10/07/2024

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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. The mortality rate associated with sepsis remains distressingly high, recorded at 32.2%. This rate escalates to 38.5% in cases that progress to septic shock, according to findings from a comprehensive meta-analysis. Rapid and accurate diagnosis is crucial in managing sepsis effectively. Traditional methods for diagnosing sepsis can be slow and may delay the initiation of treatment. 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. This system aims to support health professionals by providing timely information that could lead to faster and more accurate sepsis management. The study will examine how the AI-CDSS influences clinical decision-making and assess the confidence health professionals have in their sepsis diagnoses based on the system's assessments.

Who can participate?
Adults aged 18 years old and over who are licensed health professionals, including postgraduate year residents, residents, fellows, or attending physicians, are involved in diagnosing and managing sepsis and have at least one year of clinical experience.

What does the study involve?
Participants in this randomized controlled trial are divided into two groups: an intervention group using the AI-CDSS for sepsis diagnosis and management, and a control group following standard practices. Both groups will complete surveys assessing their confidence in sepsis management. Additionally, they will provide feedback on their experience, focusing on decision-making efficiency, ease of use, and satisfaction. This setup allows the study to compare the impact of the AI-CDSS with traditional sepsis management methods, capturing data on the effectiveness and acceptability of both approaches.

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, which could lead 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 use of 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, 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

Who is the main contact?
Dr. Hung-Sheng Shang, iamkeith@mail.ndmctsgh.edu.tw

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NIL

Study information

Scientific Title
Effectiveness of an artificial intelligence-clinical decision support system for early detection of sepsis: a randomized controlled trial

Study objectives
Primary Hypothesis:
The use of the artificial intelligence-clinical decision support system (AI-CDSS) for sepsis diagnosis and management enhances the confidence of healthcare professionals compared to those using standard diagnostic practices. This hypothesis assesses whether the intervention leads to increased confidence in clinical decisions related to sepsis management.

Secondary Hypothesis:
The implementation of AI-CDSS improves decision-making efficiency, increases user satisfaction, and enhances the overall effectiveness of sepsis management compared to conventional methods. This hypothesis evaluates the broader impact of the AI tool on improving clinical workflows and patient care outcomes.

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, Taipei City, 114202, Taiwan; +88687923311 ext 17763; tsghirb@ndmctsgh.edu.tw), ref: C202305073

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Efficacy

Participant information sheet
See study outputs table

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

Interventions

Randomized Comparison of Artificial Intelligence-Clinical Decision Support System (AI-CDSS) Use with Standard Sepsis Diagnostic Practices

This randomized controlled trial compares two groups: one using the AI-CDSS and the other following standard sepsis diagnostic practices. The intervention group receives support from the AI-CDSS, which integrates machine learning algorithms with complete blood count with differential (CBC + DIFF) data to assess the risk of sepsis. This system is designed to provide sepsis risk assessments using real-time CBC + DIFF data, supporting health professionals throughout the patient's care.

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 undergo follow-up questionnaire assessments on days 1, 2, 4, and 7 after sepsis treatment is initiated to evaluate the impact of the diagnostic approach on clinical decision-making and patient outcomes.

Intervention Type
Other

Primary outcome measure
Physician confidence in their sepsis diagnosis measured using a questionnaire on days on day 1, 2, 4, and 7 after the initial diagnosis or risk identification

Secondary outcome measures
The following secondary outcome measures will be assessed using a questionnaire administered on days 1, 2, 4, and 7 after the initial sepsis diagnosis:
1. Satisfaction with the Diagnostic Process to evaluate factors influencing physician satisfaction, including decision-making efficiency (time required and ease of accessing necessary information) and overall satisfaction with the diagnostic process as used in their clinical practice
2. Effectiveness of Sepsis Management Decisions. This involves assessing the effectiveness of the decisions made following the sepsis diagnosis in managing patient care and improving health outcomes, such as recovery rates and prevention of sepsis progression.

Overall study start date
01/06/2024

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
400

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.
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Sponsor information

Organisation
Tri-Service General Hospital

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Sponsor type
Hospital/treatment centre

Website
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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

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
31/12/2025

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			10/07/2024	No	Yes