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Testing a new AI tool to quickly identify MRSA and detect PVL genes to help improve treatment decisions

Submission date
12/09/2025

Recruitment status
No longer recruiting

Registration date
15/09/2025

Overall study status
Completed

Last Edited
12/09/2025

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
MRSA is a major cause of severe infections, particularly when strains carry Panton–Valentine leukocidin (PVL), a toxin associated with life-threatening conditions such as necrotizing pneumonia and complicated skin and soft tissue infections. Traditional diagnostic workflows are slow, typically requiring around three days for culturing and isolation, followed by species identification using complex laboratory methods (matrix-assisted laser desorption/ionization time-of-flight mass spectrometry: MALDI-TOF MS), and at least another day for antibiotic susceptibility testing (AST). Additional PCR testing for SCCmec subtyping and PVL detection further increases turnaround time and complexity.
To address this, an artificial intelligence–clinical decision support system (AI-CDSS) was developed that integrates AI algorithms with MALDI-TOF MS profiles to predict MRSA status, SCCmec subtype, and PVL presence. This study will involve health professionals who will be randomly allocated to use the AI-CDSS or continue with standard practice without the system. Participants will be surveyed to assess the effectiveness of the AI-CDSS in influencing clinical decision-making and evaluate the confidence health professionals have in antibiotic treatments based on the system's recommendations. The study aims to see how the system can accelerate MRSA molecular characterization, enable quicker, more accurate interventions, and potentially improve patient outcomes compared with current PCR-dependent workflows.

Who can participate?
Adult licensed health professionals, such as doctors, nurse practitioners, and physician assistants, who prescribe antibiotics and have at least one year of clinical experience.

What does the study involve?
Participants will be randomly divided into two groups. One group will use the AI-CDSS to assist in their clinical decision-making for patients with suspected or confirmed S. aureus infections, while the other group will continue with their usual diagnostic and prescribing practices without the AI tool. All participants will undergo a brief training session to understand how to use the AI-

CDSS. The study will track how the AI tool affects the accuracy and timeliness of MRSA and PVL-related management decisions and gather feedback from participants on their experience using the tool.

What are the possible benefits and risks of participating?
Participants may benefit from using the AI-CDSS by making more accurate and timely diagnostic and prescribing decisions, which could lead to better patient outcomes and reduced spread of antibiotic resistance. 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?
May 2025 to February 2026

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

Study information

Scientific Title
Development and validation of an AI-CDSS using MALDI-TOF MS for rapid SCCmec typing and PVL detection in MRSA and its impact on clinical decision-making: a randomized controlled trial

Acronym
AI-MRSA-PVL

Study objectives
Primary Hypothesis:
The artificial intelligence–clinical decision support system (AI-CDSS), integrating MALDI-TOF MS profiles with hierarchical machine learning, enhances physician confidence in diagnosing MRSA and identifying PVL-positive strains compared to standard practice without AI assistance. This hypothesis tests whether the intervention leads to greater confidence in selecting appropriate antibiotic treatments, isolation measures, and source control decisions on days 3, 5, 7, and 14 after treatment initiation.

Secondary Hypothesis:
The use of AI-CDSS for MRSA genotyping and PVL detection increases physician satisfaction with the diagnostic process, improves decision-making efficiency (including time required and ease of accessing necessary molecular information), enhances reliance on technological tools, and contributes to mitigating public health concerns related to antibiotic resistance and virulence factor dissemination. This hypothesis examines the overall impact of the AI tool on physician satisfaction, efficiency, and the effectiveness of MRSA management strategies on days 3, 5, 7, and 14.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 01/06/2025, Institutional Review Board of Tri-Service General Hospital (No.325, Sec.2, Cheng-Kung Rd. Neihu 11490, Taipei City, 114202, Taiwan; +88687923311; tsghirb@ndmctsgh.edu.tw), ref: C202305073

Primary study design
Interventional

Study design
Randomized controlled trial

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Antibiotic resistance

Interventions
Randomized comparison of artificial intelligence–clinical decision support system (AI-CDSS) use with standard diagnostic and prescribing practices for MRSA.

This randomized controlled trial compares two groups: one using the AI-CDSS and the other following standard diagnostic and treatment pathways without the system. The intervention group receives AI-CDSS support, which integrates AI algorithms with MALDI-TOF MS data to provide real-time MRSA genotyping, SCCmec subtype classification, and PVL detection, along with corresponding treatment guidance. The system is used at the point of care when diagnostic

and prescribing decisions are made, with the AI-CDSS interface delivering results and suggestions directly to health professionals.

Participants are randomly assigned to either the intervention (AI-CDSS assisted) or control group using a computer-generated sequence to ensure allocation concealment and reduce bias. The total duration of treatment corresponds to the length of antibiotic therapy prescribed, and follow-up assessments are conducted on days 3, 5, 7, and 14 after antibiotic treatment is initiated to evaluate clinical outcomes, user confidence, and system effectiveness.

Intervention Type
Other

Primary outcome(s)
Physicians' confidence in diagnosing and managing MRSA infections, including the identification of PVL-positive strains, will be rated by physicians for each case. Confidence will be measured using a structured questionnaire on days 3, 5, 7, and 14 after antibiotic treatment initiation.

Key secondary outcome(s)
The following secondary outcome measures will be measured using a questionnaire on days 3, 5, 7, and 14 after antibiotic treatment initiation:
1. Satisfaction with the diagnostic and prescribing process, including factors influencing satisfaction, decision-making efficiency (time required and ease of accessing molecular information), and reliance on technological tools for MRSA management, are all rated and reported by physicians.
2. The effectiveness of diagnostic-guided treatment choices in mitigating public health concerns related to antibiotic resistance and PVL-associated virulence will be assessed by physicians.

Completion date
28/02/2026

Eligibility

Key inclusion criteria
1. Medical Licensure Requirements: Participants must be licensed healthcare providers authorized to prescribe antibiotics, including residents, fellows, and attending physicians.
2. Clinical Experience: Participants must have at least one year of clinical experience to ensure they are familiar with antibiotic prescribing practices.
3. Technology Access: Participants must have regular access to computers or tablets with internet connectivity to use the AI clinical decision support system.
4. Training Commitment: Participants must be willing to complete a brief training session to learn how to properly use the AI system.

Participant type(s)
Health professional

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Limited Prescribing Authority: Healthcare practitioners without medication prescribing privileges, such as nurses, medical interns, and medical students.
2. Insufficient Clinical Experience: Healthcare providers with less than one year of clinical practice experience.

Date of first enrolment
01/10/2025

Date of final enrolment
15/02/2026

Locations

Countries of recruitment
Taiwan

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

Sponsor information

Organisation
Tri-Service General Hospital

Funder(s)

Funder type
Not defined

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