ISRCTN16278872 https://doi.org/10.1186/ISRCTN16278872

Testing a new AI tool to improve antibiotic prescriptions: a study comparing doctor decisions with and without AI support

Submission date
20/06/2024

Recruitment status
No longer recruiting

Registration date
28/06/2024

Overall study status
Completed

Last Edited
28/06/2024

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
Antibiotics are essential for treating bacterial infections, but incorrect prescribing can lead to antibiotic resistance, a significant global health concern. Traditional testing methods are slow, typically requiring on average three days for culturing and isolation, followed by species identification using matrix-assisted laser desorption/ionization time-of-flight mass spectrometry (MALDI-TOF MS), and an additional day for interpreting antibiotic susceptibility testing (AST) results, totaling at least four days. To address this, this study group developed an artificial intelligence-clinical decision support system (AI-CDSS), which integrates AI algorithms with the MALDI-TOF MS profile to predict resistance to a series of antibiotics. 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 aim is to see how the system can transform antibiotic prescribing by markedly shortening the time to identify resistant strains, thereby enabling quicker, more accurate interventions and potentially enhancing patient outcomes by delivering results about a day sooner than current methods.

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 antibiotic prescribing decisions, while the other group will continue with their usual 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 of antibiotic prescriptions 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 prescribing decisions,

which could lead to better patient outcomes and reduced 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 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

Contact name
Prof Hung-Sheng Shang

ORCID ID
https://orcid.org/0000-0002-4831-1866

Contact details
No. 325, Sec. 2, Chenggong Rd., Neihu Dist.
Taipei City
Taiwan
114202
+886 920713130
iamkeith@mail.ndmctsgh.edu.tw

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Impact of an AI clinical decision support system on antibiotic prescribing confidence: a randomized controlled trial

Acronym
AI-Assisted AntiBiotic Prescribing EXperiment (AI-ABX)

Study objectives
Primary Hypothesis: The artificial intelligence-clinical decision support system (AI-CDSS) enhances physician confidence in antibiotic prescribing compared to standard practice without AI assistance. This hypothesis tests whether the intervention leads to greater confidence in selecting appropriate antibiotic treatments on days 3, 5, 7, and 14 after treatment initiation.

Secondary Hypothesis: The use of AI-CDSS in antibiotic prescribing increases physician satisfaction with the prescription process, improves decision-making efficiency (including time required and ease of accessing necessary information), enhances reliance on technological tools, and is effective in mitigating public health concerns related to antibiotic resistance. This hypothesis examines the overall impact of the AI tool on physician satisfaction, efficiency, and the effectiveness of antibiotic choices on days 3, 5, 7, and 14.

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; +88687923311; 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
Antibiotic resistance

Interventions
Randomized comparison of artificial intelligence-clinical decision support system (AI-CDSS) use with standard antibiotic prescribing practices

This randomized controlled trial compares two groups: one using the AI-CDSS and the other following standard antibiotic prescribing practices. The intervention group receives AI-CDSS support, which integrates AI algorithms with MALDI-TOF MS data to provide real-time antibiotic resistance predictions and prescribing recommendations. The system is used at the point of care when 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 blinding and reduce allocation 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 long-term health outcomes and system effectiveness.

Intervention Type
Other

Primary outcome measure
Physician confidence in antibiotic prescribing will be rated by physicians for each case, measured using a questionnaire on days 3, 5, 7, and 14 after antibiotic treatment initiation

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

Overall study start date
01/06/2024

Completion date
14/01/2025

Eligibility

Key inclusion criteria
1. Professional Status: Must be a licensed health professional authorized to prescribe antibiotics, including postgraduate year residents, residents, fellows, or attending physicians.
2. Clinical Experience: Must have a minimum of one year of clinical experience, ensuring familiarity with antibiotic prescribing practices.
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.
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.

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-prescribing Roles: Health professionals who do not have the authority to prescribe medications, such as nurses without prescribing rights, medical interns, or medical students.
2. Inexperience in Prescribing: Health professionals with less than one year of clinical experience, ensuring all participants have adequate exposure to antibiotic prescribing practices.

Date of first enrolment
01/07/2024

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

Sponsor details

No. 325, Sec. 2, Chenggong Rd., Neihu Dist.
Taipei City
Taiwan
114202
+886 287923311
medr@mail.ndmctsgh.edu.tw

Sponsor type
Hospital/treatment centre

Website
https://www.tsgh.ndmctsgh.edu.tw/

ROR
https://ror.org/007h4qe29

Funder(s)

Funder type
University/education

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			28/06/2024	No	Yes