Official Study Title

Exploration of diagnosis and treatment strategies and prognostic prediction models for acute respiratory distress syndrome based on radiographic evaluations assessed by artificial intelligence.

ClinicalTrials.gov Identifier: Not yet assigned.

Document Type: Informed Consent Form.

Document Date: December 12, 2025.

Study Sponsor / Institution: Zhongshan Hospital, Fudan University.

INFORMED CONSENT FORM

Participant Information Sheet

Protocol Title: Exploring AI-based Imaging Assessment for ARDS Diagnosis, Treatment Strategy, and Prognostic Prediction Model: A Retrospective Observational Study

Principal Investigator: Minjie Ju

Sponsor: Zhongshan Hospital, Fudan University

Dear Participant,

You are invited to participate in the research study titled **Exploring AI-based Imaging Assessment for ARDS Diagnosis, Treatment Strategy, and Prognostic Prediction Model: A Retrospective Observational Study**. Please read this informed consent form carefully and consider your decision to participate. Your participation is entirely voluntary. You may only enter the study after signing this form. Your study doctor or research staff will explain any parts you do not understand. We encourage you to discuss your decision with family or friends before agreeing to participate.

You have the right to refuse participation or withdraw from the study at any time without penalty or loss of benefits to which you are otherwise entitled. If you are currently participating in another study, please inform your study doctor or research staff.

The following provides important information about the study background, purpose, procedures, and other key details:

Study Background

Acute Respiratory Distress Syndrome (ARDS) is a life-threatening, non-cardiogenic pulmonary edema triggered by various pulmonary (e.g., pneumonia, aspiration) or extrapulmonary (e.g., sepsis, acute pancreatitis, trauma) factors. It leads to severe hypoxemia, reduced lung compliance, increased shunt, and elevated dead space.

ARDS accounts for approximately 10% of ICU admissions and carries a high mortality risk correlated with disease severity. Despite being common in ICUs, clinician recognition remains limited; an estimated 40% of ARDS cases are undiagnosed, suggesting underestimated incidence. ARDS is a highly heterogeneous disease with varied etiologies, inflammatory phenotypes, and histological features, requiring

individualized treatment strategies based on deep understanding of its pathophysiology. This complexity has contributed to relatively slow therapeutic progress. Early diagnosis and personalized management are therefore crucial.

Assessment of pulmonary edema is central to ARDS diagnosis. Chest X-ray or CT can visualize or quantify edema and help exclude cardiogenic causes, forming key diagnostic evidence. In resource-limited ICU settings, chest CT serves as an important tool for evaluating lung involvement and patient triage. Quantitative CT may provide more information than conventional radiography.

Artificial Intelligence (AI) is widely applied in drug development, disease diagnosis, healthcare planning, monitoring, digital consultation, surgery, and clinical practice. AI can assist in ARDS identification, diagnosis, risk stratification, severity/event prediction, management, mortality prediction, and decision-making. Particularly in medical imaging, Deep Learning (DL) has demonstrated high efficiency and accuracy in image recognition and analysis, aiding clinical practice with X-ray and CT. Thus, AI holds potential value in ARDS diagnosis, treatment, and prognosis assessment. AI-based evaluation can perform quantitative analysis of lung images, identify imaging biomarkers and their changes, and assist physicians in disease assessment and treatment evaluation.

Study Purpose

This study aims to analyze the clinical characteristics and chest computed tomography (CT) images of ARDS patients in the ICU, explore AI-based diagnosis and treatment strategies, and predict patient prognosis.

Study Procedures

How many people will take part?

Approximately 400 participants will be enrolled in this study conducted at Zhongshan Hospital, Fudan University.

Study Steps

If you agree to participate, please sign this informed consent form.

Screening Phase: After you sign the consent form, the doctor will inquire about and record your medical history, collect data such as chest CT images, and determine your eligibility based on the study's inclusion and exclusion criteria.

Enrollment Phase: If you are eligible, the following retrospective data will be collected from your electronic medical records:

General Information: Age, gender, BMI, comorbidities (chronic kidney disease,

coronary heart disease, hypertension, diabetes, cirrhosis, HIV/AIDS, etc.), primary cause of ARDS, and receipt of mechanical ventilation, high-flow oxygen therapy, or ECMO.

Physiological Parameters: Temperature (T), heart rate (HR), respiratory rate (RR), peripheral oxygen saturation (SpO_2), mean arterial pressure (MAP).

Laboratory Parameters: pH, arterial partial pressure of oxygen (PaO_2), fraction of inspired oxygen (FiO_2), arterial partial pressure of carbon dioxide ($PaCO_2$), lactate (Lac), platelet count (PLT), white blood cell count (WBC), hemoglobin (Hb), serum creatinine, C-reactive protein (CRP), procalcitonin (PCT), international normalized ratio (INR), brain natriuretic peptide (BNP), interleukin-6 (IL-6).

Ventilator/High-Flow Parameters: Positive end-expiratory pressure (PEEP), tidal volume (TV), plateau pressure (Pplat), flow rate.

Other Parameters: Sequential Organ Failure Assessment (SOFA) score, Acute Physiology and Chronic Health Evaluation II (APACHE-II) score.

How long will the study last?

This is a retrospective observational study. The study itself does not involve any additional examinations, treatments, or follow-up arrangements.

You may withdraw at any time without losing any entitled benefits. We encourage you to discuss withdrawal with your doctor first. You may also be withdrawn if you experience a serious adverse event, if your doctor believes continuation is not in your best interest, or if required by the sponsor or regulatory authorities. Withdrawal will not affect your normal medical care or rights.

Biological Specimens

This is a retrospective study involving only data collection. No biological samples will be collected.

Risks and Benefits

What are the risks?

The main risk involves potential disclosure of personally identifiable or sensitive information from your medical records or personal data, despite coding procedures. Every effort will be made to protect your information within legal limits.

What are the benefits?

There may be no direct benefit to you. However, information obtained may benefit

future patients with similar conditions.

Alternative Treatments

This study involves only data collection. No alternative treatments are offered through this study.

Confidentiality

The research team may access your medical history and necessary records for study purposes. By signing, you permit the team to contact other healthcare providers for relevant information. Only study team members will have access to identifiable information. Authorized monitors, auditors, the Ethics Committee, and regulatory authorities may inspect original records for data verification, respecting confidentiality and regulations.

Your personal information and study data will be coded to prevent direct identification. Results published or presented will not disclose your identity.

You may withdraw your consent for data use at any time by contacting your study doctor, which will result in your withdrawal from the study. No new identifiable data will be collected thereafter, but data already collected may continue to be used as described. To maintain scientific integrity, you may not access some study-related records until the study ends. Afterwards, you may request to see your collected health data and correct any errors.

Coded research data will be stored at Zhongshan Hospital, Fudan University, for 5 years after study completion and then destroyed. Your information will not be reused for other purposes.

Feedback of Results

The final study results will not be shared with you as they are not intended for guiding your individual treatment.

Costs and Compensation

Study-related costs: This study involves no drugs, devices, or additional tests. There are no extra costs to you. Routine treatments and tests for other conditions are not covered.

Compensation: No compensation is provided as the study imposes no additional burden.

Compensation for injury

As a retrospective study without interventions, if any study-related injury occurs, you are entitled to free treatment provided by the sponsor or compensation according to Chinese law.

Participant Rights and Notes

Your rights: Participation is voluntary. Refusal or withdrawal will not affect your standard care. You may withdraw anytime without discrimination. You will be re-consented if significant new information affecting your participation emerges.

Important notes: The study respects participant rights and privacy, protects personal information, avoids unnecessary harm or risk, and ensures informed consent and autonomy.

Contact Information

If new significant information arises during the study, your doctor will inform you. For questions about your data or the study findings, contact:**Minjie Ju** at ju.minjie@zs-hospital.sh.cn.

This study has been approved by the Ethics Committee. For questions regarding your rights/ welfare, to report difficulties, complaints, concerns, or to provide feedback, contact:

Ethics Committee of Zhongshan Hospital, Fudan University
Phone: 021-31587871
Email: ec@zs-hospital.sh.cn

PARTICIPANT SIGNATURE PAGE

Statement of Informed Consent:

I have been informed about the purpose, background, procedures, risks, and benefits of this study. I have had sufficient time and opportunity to ask questions, and my questions have been answered satisfactorily. I agree to participate.

I have been informed whom to contact with questions, concerns, suggestions, or for further information or assistance.

I understand that I may choose not to participate or may withdraw at any time without reason.

I understand that I may be withdrawn if my condition worsens, if I experience a serious adverse event, if my doctor believes continued participation is not in my best interest, or if the sponsor or regulatory authorities require study termination. In such cases, my doctor will notify and discuss alternatives with me.

I will receive a copy of this signed consent form.

I understand that my personal information is necessary for this research and I consent to its use and processing as described herein.

☐ I agree to participate.

☐ I do not agree to participate and understand I cannot join this study.

Participant Signature Date:

Guardian Signature Relationship to Participant Date:
(Required if participant lacks/ has limited capacity to consent)

Impartial Witness Signature Date:
(Required if participant cannot read this form)

Investigator Signature Date: