informed consent

Project name: Comparison of traditional regression model and AI to predict prolonged ICU stay after head and neck tumors

Sponsor: Sun Yat-sen Memorial Hospital of Sun Yat-sen University

Principal investigator: Chief physician Yang Zhengfei

Version number: V1.0

Version date: 2024.3.21

Informed consent form Informed notification page

Dear subjects:

We invite you to volunteer for the "The traditional regression model versus AI to predict prolonged ICU stay after head and neck cancer surgery."The principal investigator of this study was Chief Physician Zhengfei Yang. This study has been approved by the Medical Ethics Committee of Sun Yat-sen Memorial Hospital, Sun Yat-sen University.

Please read the following information carefully before you decide whether to participate in this study. If you have learned more about the study and decide to participate, you will need to sign this informed consent form.

1. research background

Patients with head and neck tumors are often transferred to ICU due the need for life support, but long ICU stay is unfavorable for patients, so early identification of patients with prolonged ICU stay is crucial to shorten the ICU stay time. However, the traditional prediction models are insufficient in predicting the ICU transfer of patients. With the development of AI, the use of AI to predict patient stay time in the ICU has been widely studied in the clinic.

2. purpose of research

Comparing the prediction accuracy of AI and traditional prediction models for ICU stay time after head and neck tumors.

3. Introduction of the clinical research project

1. Study design: This study is a non-interventional study, with a total of 700 subjects enrolled, and the main entry criteria are.

Selection criteria

- Patients after surgery for head and neck tumors
- Age was older than 18 years.

Exclusion criteria

- Patients were transferred to ICU two times after head and neck tumors
- Patients with unplanned ICU transfer

2. Study time limit: March 2024-March 2025

4. Process of the clinical study

After signing the informed consent, the study doctor will use the data of the patient in ICU, including baseline data of the admission: age, gender, body mass index, past history [including oral cancer treatment (radiotherapy, chemotherapy, immunotherapy), previous basic disease history (hypertension, diabetes, etc.)], personal history (including smoking and drinking), family history of oral cancer, surgical information, test results, and imaging results. Using these data into the AI model to predict the time of ICU transfer, participation in this study will not interfere with your routine diagnosis and treatment.

VI. Expenses related to this study

This study was a non-interventional study and all variables included in the model were commonly used clinical variables without the need to add new tests or examinations. Participation in this study will not add extra to your financial burden.

7. Possible benefits

This study is a non-interventional study, and the results may not be directly used for your diagnosis and treatment. However, the testing of your samples or the analysis of medical data will help further medical research and understanding of such diseases, and hope to improve the diagnosis and treatment of diseases in the future.

VIII. Possible risks

This study is non-interventional and will not affect or interfere with your routine practice, thus will not increase your risk. If you have any questions during the study, you may consult with the study doctor or the ethics committee.

IX. Confidentiality measures

The results of this clinical study are only used for scientific purposes, so your personal data in your study and study are confidential and will be protected in accordance with the law. Your name and identity will not be disclosed and your name will not appear in any study report or public publication. Government management departments, hospital ethics committees, researchers, if required, have the right to contact all your research data, including clinical observation form, test data, etc.

Ten, rights

This study has been reviewed and approved by the Medical Ethics Committee of Sun Yat-sen Memorial Hospital, Sun Yat-sen University. The protocol design is consistent with the ethical requirements, which will guarantee that your rights and interests will not be infringed in this study.

Your participation in this clinical study is entirely voluntary, you may refuse to participate or withdraw at any time without discrimination or retaliation, and your medical treatment and interests will not be affected. If the doctor thinks you are not fit to continue during the study, the doctor has the right to continue the study to protect your interests. In addition, you may have information about the study during the study. If we are updated about this study, we will inform you to decide whether to continue in the study.

Eleven, detailed contact information

If you have any concerns or questions about participating in this study, or if you experience any abnormal reactions while participating in this study, or in case of an emergency, you should contact:

Doctor: Tang Junpeng Tel: 17724279629

If you have any complaints or concerns or doubts about the way the study is conducted by the study physician, as the right of the study subject, you may contact the Medical Ethics Committee of the Center:

Email address: sysyxllwyh@163.com Contact Number: 020-81332587

Informed consent form, consent signature page

Subjects stated that

1、 I have read the informed consent form carefully, and the researchers have given me detailed explanations and answered my relevant questions. I am fully aware of the following contents:

（1） As a subject, I will comply with the subject information requirements, volunteer to participate in the study, and will fully cooperate with the researchers to truthfully and objectively provide the researchers with their health status and related information before participating in the study.

（2） I agree with Sun Yat-sen Memorial Hospital of Sun Yat-sen University for the purpose of scientific research purposes. I understand that the results of this clinical study are only used for scientific research purposes, except for government management departments, ethics committees, researchers, etc. My personal data in the study and research are confidential and will be protected in accordance with the law.

（3） My participation in this study is completely voluntary, I can refuse to participate or withdraw from the study at any time without discrimination or retaliation, and my medical treatment and interests will not be affected.

At the same time I declare:

（1） I am willing to follow the research process;

（2） This informed consent form has been received.

Subjects signed: contact way:

date: year moon sun

Sign of subject guardian (if necessary): Relationships with the Subject: Contact Information:

date: year moon sun

Witness signature (if necessary): contact way:

date: year moon sun

The researcher's statement

2. I have fully explained and explained to the subject the purpose of the study, the study methods, operating procedures, and the possible risks and potential benefits of the subject's participation in the study, and answered all relevant questions of the subject satisfactorily.

Signature of Investigator (informing subject): contact way:

date: year moon sun