Ultrasound-assisted vs. real-time ultrasound-guided paracentral approach combined lumbar and epidural anesthesia in elderly patients: a randomized controlled study

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Informed consent

Dear patient,

We sincerely invite you to participate in the project "**Ultrasound-assisted vs. real-time ultrasound-guided paramedical Approach combined lumbar and epidural anesthesia in elderly patients: a randomized controlled study**". The study will be conducted at Tongji Hospital affiliated to Tongji Medical College of Huazhong University of Science and Technology, and an estimated 96 participants will voluntarily participate. This study has been reviewed and approved by the Medical Ethics Committee of Tongji Hospital, Tongji Medical College, Huazhong University of Science and Technology.

This informed consent form provides you with information to help you decide whether or not to participate in the clinical study. Your participation in this study is voluntary. This study has been reviewed by the Ethics Committee of the research institution.

Please read it carefully and address any questions to the researcher in charge of the study.

Research purpose:

Traditional body surface marker guided intraspinal anesthesia can meet most of the clinical anesthesia needs, but for the presence of obesity, spinal deformity, senile ligament calcification, previous lumbar surgery history, etc., intraspinal puncture often has technical difficulties. Ultrasound-guided intraspinal puncture can provide anatomical information related to the puncture site, including intervertebral segment, posterior median line of the spine, vertebral canal depth, and distribution characteristics of each ligament, providing a solution for difficult puncture and improving the accuracy and safety of intraspinal puncture.

According to the clinical experience of our center in using ultrasound-guided intraspinal operation, we believe that different ultrasonic application methods are also important factors affecting the success rate of intraspinal puncture and shortening the puncture time, and their conclusions may be different from those of Chen L et al.

Therefore, we designed this study to explore the difference between the clinical effects of ultrasus-assisted positioning by experienced operators and real-time ultrasus-guided paramedical approach combined epidural anesthesia, so as to provide validation for clinical use and promotion of real-time intraspinal ultrasound technology.

Research program:

This study was a prospective randomized controlled study, and the anesthetic regimen was no different from that used in conventional surgery. You will be interviewed pre-operatively to gather relevant information and directed to use the Verbal Numerical Pain Rating Scale (VNRS). Once in the operating room, your information will be checked, vital signs will be monitored, and routine ultrasound guided intraspinal anesthesia will begin. We will ask you about your satisfaction with this procedure and possible adverse reactions after the end of the spinal anesthesia.

Possible benefits of research:

In this study, ultrasound visual equipment was used to perform ultrasound assisted positioning and real-time ultrasound guided paramedical approach combined lumbo-epidural anesthesia. Compared with traditional palpation for combined epidural anesthesia, both methods have been proved to shorten the operation time and improve the success rate of puncture.

Study risk and discomfort:

According to the report, compared with the traditional palpation method, no new risks and discomfort have been found in the two technologies of ultrasound assisted positioning and real-time ultrasound guidance. If any adverse conditions or effects are observed during diagnosis and treatment, the research doctor or the anesthesiologist in charge will immediately deal with them. In special cases, the anesthesiology department can also be contacted at 13707197324.

Alternative treatment options:

The maximum number of skin piercings is 6, and the cumulative redirection of each skin piercing is not more than 6 times. If six skin piercings are unsuccessful, consider traditional palpation, changing the puncture space, or general anesthesia.

Privacy protection:

The personal information of any patient participating in the study will be kept confidential, and unless you have given your permission, you do not have to worry about anyone other than a member of the study group accessing your hospitalization information from the study. Your medical records will be kept in their entirety at the hospital where you visited, and researchers, ethics committees, and drug regulatory authorities will be allowed access to your medical records. For example, your group status, pain score will be identified by the study number, number, and not by your name. In addition to not disclosing your information during the research process, we will not disclose your personal identity in the presentation of the research results, and we will destroy the collected research data after the research results are published. In order to ensure that the research is carried out in accordance with the regulations, the government administration or the members of the ethics review committee can access your personal data at the research facility as required.

Fees and compensation:

The drugs and procedures involved in the study are clinical routine. The treatment and examination required for other diseases or complications that you have at the same time will be at your own expense. If you are injured as a result of your participation in the study: In the event of an injury related to the clinical study rather than the clinical treatment, you may receive free surgery, examination, treatment, and/or corresponding compensation at the expense of the Investigator Program Grant.

Voluntary participation and free withdrawal:

As a subject, you can keep abreast of information and research progress related to this study, and voluntarily decide (to continue) to participate or not (to continue) to participate. After participating in the study, regardless of whether the injury has occurred, or whether it is serious, you can choose to notify the researcher at any time to request withdrawal from the study, your data will be determined according to your wishes to be included in the study results, and any of your medical treatment and rights will not be affected. If you continue to participate in the study, you will cause serious harm and the investigator will terminate the study.

During the study period, please provide truthful information about your medical history and current physical condition; Tell the study doctor about any discomfort you have experienced during the study; Do not take restricted drugs, food, etc.; Tell the research doctor if you have participated in other studies recently or are currently participating in other studies. The study physician may terminate your participation in the study if you do not follow the study plan, or if you suffer a study-related injury or for any other reason.

Contact information:

If you have any questions related to this study, or if you have any discomfort or injury during the study, or if you have any questions about the rights and interests of participants in this study, you can contact the primary anesthesiologist. In special cases, please contact the Department of Anesthesiology at _____.

Informed consent Signature:

I have read this informed consent form, and my doctor (signed) has explained the purpose, content, risks and benefits of this clinical trial to me in detail, and answered all the questions I asked. I have been aware of this clinical study, and I am willing to participate in this study.

The subjects signature: date: _____

The researchers signature: date: _____

Researcher contact number: _____