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Informed Consent

Dear Sir/Madam：

We invite you to participate in the research project titled “Effects of head direction during prone position on postoperative delirium in elderly patients undergoing thoracolumbar spine surgery: a randomized controlled trial”. This study is led by Chief Anesthesiologist, Qian Bin, at The First people's Hospital of Yancheng and will be conducted at this hospital, with an estimated 500 participants volunteering to take part. The study has been reviewed and approved by Yancheng No. 1 People's Hospital Ethics Examination Committee, with the diary number: 2023-K-120-01.

Why is this research being conducted?

Postoperative delirium (POD) is an acute, fluctuating neuropsychiatric syndrome characterized by disturbances in attention, awareness, and cognition, typically manifesting within five days post-surgery. It is the most common postoperative complication in older adults. Recent meta-analyses report that the incidence of POD in elderly patients undergoing spinal surgery ranges from 3.8% to 40.4%, often associated with adverse clinical outcomes.

In thoracolumbar spine surgeries, head positioning – whether neutral or with lateral deviation – is typically based on clinical considerations. However, some studies suggest that head rotation may affect cerebral hemodynamics, which may potentially affect the incidence of POD. Epidemiological studies on POD have seldom considered the influence of head orientation during spinal surgery. It is unknown whether the intraoperative head orientation in the prone position contributes to POD in older adults. Thus, the primary aim of this study is to assess the impact of head direction during prone positioning on the incidence of POD in elderly patients undergoing thoracolumbar spine surgery. Our secondary aim is to investigate the effects of head direction on cerebral hemodynamics and oxygenation during prone positioning.

Who is (not) suitable to participate in the study?

1. Inclusion criteria
    - Age ≥ 65 years.
    - American Society of Anesthesiologists (ASA) physical status class II–III.
    - Mini-Mental State Examination (MMSE) score > 23 points, assessed one day preoperatively.
    - Expected duration of surgery > 2 h.
2. Exclusion criteria
    - Cervical spine trauma.
    - Restricted head positioning.
    - Cervicogenic dizziness and vertigo.
    - Central nervous system disorders with clinical manifestations.
    - Communication impairments.
    - Psychiatric disorders.

If you participate in the study, what do you need to do?

If you are willing to participate in this study, you will have a 1/2 chance of receiving one of the following two treatment plans: prone positioning with the head turned to one side, or prone positioning with the head in a neutral position. We will regularly assess your cognitive function and collect data related to cerebral perfusion and oxygenation during the week you undergo treatment, at the following time points: one day before surgery, intraoperatively, and postoperatively on days 1 to 5.

What are the benefits of participating in a study?

Whether or not you participate in this study, your condition will be diagnosed and treated in a timely manner. There is no direct benefit to you from participating in this study. However, the information gathered from your participation may provide valuable insights for future patients undergoing similar treatments.

What are the risks of participating in a study?

This study is a prospective randomized controlled trial. There is currently no guideline consensus on the effect of head position during thoracolumbar spine surgery, and its impact on the incidence and severity of postoperative delirium is still inconclusive. In this study, apart from the prone positioning with head tilt as the research variable, all other anesthesia, surgical treatments, and postoperative care will follow standardized protocols. During the study, if you experience any discomfort or adverse reactions, please contact the study physician immediately. Additionally, any treatment may be ineffective, and there is a possibility that the condition may continue to progress due to treatment failure or the presence of other comorbid conditions.

Are there any costs associated with participating in the study?

To compensate for any inconvenience caused by your participation in this study, we will cover the costs of cerebral oxygen saturation monitoring and transcranial ultrasound examinations during the study. However, the cost of a one-time cerebral oxygen saturation monitoring probe is not included in the free coverage. Any treatment and examinations required for comorbid conditions, as well as costs for alternative treatments if the current treatment proves ineffective, will not be covered. This study is conducted during your hospitalization, and there will be no reimbursement for transportation, lost wages, or nutritional expenses. In the event of any trial-related harm, appropriate treatment and compensation will be provided in accordance with national regulations.

Is personal information confidential?

Your medical records will be kept at the hospital, and the researchers, research oversight bodies, and ethics examination committee will be allowed to access your medical records. Any public reports related to the results of this study will not disclose your personal identity. We will make every effort to protect the privacy of your personal medical information to the fullest extent permitted by law.

What other treatment options are available if you choose not to participate in this study?

You may choose not to participate in this study, and this will not have any negative impact on your access to standard treatment.

Do I have to participate in the study?

Participation in this study is entirely voluntary. You have the right to decline participation or withdraw from

the study at any time during the research process, and this will not affect the treatment provided by your doctor. If you decide to withdraw, please contact your doctor, and you may be asked to undergo relevant examinations, which will be beneficial for protecting your health.

If you have any concerns regarding your personal rights, you may contact the Ethics Review Committee of this hospital at the following phone number: 0515-66696823.

Participant Statement:

I have read the above information regarding this study and fully understand the potential risks and benefits of participating. I voluntarily agree to participate in this study. I will receive a signed copy of this informed consent form with my name and the date.

☐ I agree to participate in the research project titled “Effects of head direction during prone position on postoperative delirium in elderly patients undergoing thoracolumbar spine surgery: a randomized controlled trial”.

☐ I agree that data about me is processed in the manner described in the information.

Place and date	Signature

Personal identification number	Name printed

Investigator's Statement:

I confirm that I have explained the details of this study to the participant, particularly the potential risks and benefits of participating, and have answered all questions raised by the participant. The participant has voluntarily agreed to participate in this study. This informed consent form is made in two copies, one for the investigator and one for the participant, each with a signed copy."

Place and date	Signature

Personal identification number	Name printed