



参与临床实验知情同意书

尊敬的患者/患者家属/法定代理人：

您/您的家人/被监护人目前因病情需要，在重症监护室接受治疗。我们邀请他/她参与一项结合脓毒性休克液体复苏与经颅多普勒超声检查的研究。在您决定是否同意参与前，请仔细阅读以下内容。

一、 检查与研究的介绍

检查目的： 经颅多普勒是一种无创的超声检查，通过头颅骨窗探测脑内主要血管的血流速度，用于评估重症患者的脑血流灌注、脑血管痉挛、颅内压变化等情况，为临床诊断和治疗提供重要参考。

研究目的： 在完成临床诊断所需检查的同时，我们将本次检查所获得的图像、血流频谱及相关的匿名化数据，用于评估液体复苏治疗对脑供血的影响的医学科学研究。

检查过程： 检查由经医院考核并授权的熟练医师操作。将在患者的颞部（太阳穴附近）、眼部或枕部涂抹超声耦合剂，然后用一个小的超声探头进行探查。整个过程无创、无痛，通常持续约 20-30 分钟。检查将在患者病情允许的情况下进行。

声明：本研究已通过临床伦理学论证，伦理批件号：2021-156-01

二、 可能带来的益处和风险

潜在益处：

1.患者能直接获得专业的脑血流动力学评估，有助于医生全面了解病情。

您贡献的数据可能对未来医学发展和改善其他患者的治疗做出贡献。

2.潜在风险与不适：本检查被认为是安全的，风险极低。操作时探头对头皮的压迫可能带来轻微不适，但通常可以耐受。

对于极度躁动的患者，为保障检查安全和数据质量，医生可能会根据情况使用镇静药物，这属于重症患者的常规医疗措施，其风险与获益已由主管医生进行专业评估。

三、 隐私保密

您的隐私将得到严格保护。所有用于科学研究的检查数据都将进行**匿名化处理**，即移除患者的姓名、身份证号、住院号等所有个人身份信息，并以一个研究编号代替。

研究结果可能在医学期刊上发表或在学术会议上交流，但绝不会泄露您的任何个人身份信息。

患者的病历记录和本次检查的临床报告将按医院规定严格保密。

四、 自愿原则

参与本研究是完全自愿的。无论您是否同意参与，都不会影响您的家人/被监护人现在和将来在本院接受的任何医疗服务质量和待遇。

您有权在任何时候决定退出本研究，而不会带来任何不利后果。如果您决定退出，只需告知您的主管医生或研究人员，我们将停止使用其数据用于后续研究（但已完成的匿名化数据分析可能无法撤回）。

五、 联系人信息

如果您对本次检查或研究有任何疑问，可以随时联系：

主要研究者/负责人： 于晴 **职称：** 主治医师 **联系电话：** 0755-29821111-04107

如果您对参与本研究的权益有任何疑问或投诉，可以联系本院伦理委员会：

伦理委员会办公室联系电话： 0755-28020377

患者声明与签署（如果患者意识清醒且有能力）

本人已阅读并理解了上述内容，所有疑问均已得到解答。我自愿同意参与本次经颅多普勒超声检查及相关科学研究。

患者签名： _____

日期： ____年____月____日

关系人： _____ (如为代理人代签，请填写与患者关系)

法定代理人/家属声明与签署（适用于患者无同意能力时）

本人作为患者 _____ (患者姓名) 的法定代理人/直系亲属，已阅读并完全理解上述内容，所有疑问均已得到解答。我代表他/她，同意参与本次经颅多普勒超声检查及相关科学研究。

代理人签名： _____

与患者关系： _____ (请注明：父母/子女/配偶等)

日期： _____年____月____日

联系电话： _____

医生/研究人员声明

本人已向患者家属/法定代理人详细解释了本次经颅多普勒超声检查和研究的目的、过程、潜在益处和风险，并确认其已理解。

医生/研究人员签名： _____

日期： _____年____月____日



Translation:

To the Patient/Family Member/Legal Representative of the Patient:

You/ your family member/ward is currently receiving treatment in the Intensive Care Unit due to their medical condition. We invite him/her to participate in a research study integrating fluid resuscitation for septic shock with Transcranial Doppler ultrasound examination. Before you decide whether to provide consent for participation, please read the following information carefully.

Introduction to the Examination and Research

Purpose of the Examination: Transcranial Doppler is a non-invasive ultrasound examination that detects blood flow velocity in the major intracranial vessels through acoustic bone windows. It is utilized to assess cerebral blood flow perfusion, cerebral vasospasm, intracranial pressure changes, and other parameters in critically ill patients, thereby providing essential reference information for clinical diagnosis and treatment.

Purpose of the Research: In addition to fulfilling the requirements for clinical diagnosis, we intend to utilize the images, flow spectra, and related anonymized data obtained from this examination for medical scientific research aimed at evaluating the impact of fluid resuscitation therapy on cerebral blood supply.

Examination Procedure: The examination will be performed by a proficient physician who has been certified and authorized by the hospital. Ultrasound

coupling gel will be applied to the patient's temporal regions (near the temples), ocular regions, or occipital area, following which a small ultrasound probe will be used for scanning. The entire procedure is non-invasive and painless, typically lasting approximately 20-30 minutes. The examination will be conducted contingent upon the stability and suitability of the patient's condition.

Statement: This study has been reviewed and approved by the Clinical Ethics Committee. Ethics Approval Document Number: 2021-156-01

Potential Benefits and Risks

Potential Benefits: The patient will directly receive a specialized assessment of cerebral hemodynamics, which may assist the treating physicians in gaining a more comprehensive understanding of the clinical status.

The data you contribute may aid future medical advancements and improve treatment strategies for other patients.

Potential Risks and Discomforts: This examination is considered safe, with a very low risk profile. Minor discomfort may arise from the pressure applied by the probe on the scalp during operation, but this is generally well-tolerated.

For patients exhibiting extreme agitation, and to ensure both procedural safety and data quality, the physician may administer sedative medications based on clinical judgment. This constitutes a routine medical measure in the

management of critically ill patients, for which the risks and benefits have been professionally evaluated by the attending physician.

Privacy and Confidentiality

Your privacy will be strictly protected. All examination data utilized for scientific research purposes will be subjected to **anonymization processing**. This entails the removal of all personally identifiable information, such as the patient's name, national identification number, and hospital admission number, which will be replaced by a unique research code. The findings of this research may be published in medical journals or presented at academic conferences; however, under no circumstances will any personally identifiable information be disclosed. The patient's medical records and the clinical report generated from this examination will be maintained in strict confidence in accordance with hospital regulations.

Voluntary Participation

Participation in this research is entirely voluntary. Your decision regarding participation will **not** affect the quality or standard of any current or future medical services provided to your family member/ward at this institution. You retain the right to withdraw from this study at any time without incurring any penalty or loss of benefits. Should you decide to withdraw, simply notify the attending physician or a member of the research team. Upon withdrawal, we will cease using the participant's data for any subsequent research activities

(noting that it may not be feasible to retract anonymized data that has already been incorporated into completed analyses).

Contact Information

If you have any questions regarding this examination or the research study, please feel free to contact:

Principal Investigator/Responsible Person: Yu Qing **Title:** Attending Physician **Contact Phone:** 0755-29821111- 04107

If you have any questions or concerns regarding your rights as a participant in this study, you may contact the Hospital Ethics Committee:

Ethics Committee Office Contact Phone: 0755-28020377

Patient Statement and Signature (If the patient is conscious and possesses decision-making capacity): _____

I have read and understood the information presented above, and all my inquiries have been satisfactorily addressed. I voluntarily consent to participate in this Transcranial Doppler ultrasound examination and the associated scientific research.

Patient Signature: _____

Date: _____

Witness Name: _____ (If signed by a representative, please indicate relationship to the patient)

Legal Representative/Family Member Statement and Signature

(Applicable when the patient lacks capacity to consent)

As the legal representative/immediate family member of the patient _____ (Patient's Name), I have read and fully comprehended the information provided above, and all my questions have been answered. On his/her behalf, I provide consent to participate in this Transcranial Doppler ultrasound examination and the related scientific research.

Representative Signature: _____

Relationship to Patient: _____ (e.g., Parent/Child/Spouse)

Date: _____

Contact Phone: _____

Physician/Researcher Statement

I have thoroughly explained the purpose, procedures, potential benefits, and risks associated with this Transcranial Doppler ultrasound examination and

research study to the patient's family member/legal representative and have confirmed their understanding.

Physician/Researcher Signature: _____

Date: _____