伦理审查批件 ER.03.03-V1.04

Ethical Approval Document

山东省泰山医院医学伦理委员会

Research Ethical Committee of Shandong Taishan hospital

伦理审查批件

审批号：2017BL-045-01

Ethical Approval Document Approval number: 2017BL-045-01

项目名称 Research name	前列地尔治疗 ICU 并发 AKI 患者的疗效及对肾脏阻力指数、尿氧分压的影响 Effect of alprostadil on renal resistance index and urinary oxygen partial pressure in ICU patients with AKI		
项目来源 Funding	泰安市科技计划课题“首都特色”项目 Beijing Municipal Science & Technology Commission		
临床研究负责单位 Research Institution	山东省泰山医院 Shandong Taishan hospital		
本院主要研究者 Investigator	贾燕 Jia Yan		
审查类别 Approval category	初始审查 First Review	审查方式 Approval procedure	会议审查 Meeting Review
审查日期 Review date	2017 年 7 月 18 日 18 July 2017		
审查地点 Review Institution	山东省泰山医院 Shandong Taishan hospital		
批准文件 Approval files	研究方案：版本号：VERSION1.0_20170613，版本日期：2017/06/13； Assignment for technical design (Version1.0_20170613; Date: 2017/06/13). 知情同意书：版本号：VERSION1.0_20170613，版本日期：2017/06/13； Informed consent form (Version1.0_20170613; Date: 2017/06/13). 病例报告表：版本号：VERSION1.0_20170613，版本日期：2017/06/13； Case report form (Version1.0_20170613; Date: 2017/06/13). 日记卡：版本号：VERSION1.0_20170613，版本日期：2017/06/13； Headache Diary (Version1.0_20170613; Date: 2017/06/13). 招募材料：版本号：VERSION1.0_20170613，版本日期：2017/06/13； Recruitment material (Version1.0_20170613; Date: 2017/06/13).		
审查结果 Review comment	同意 10 票 Approval 10	不同意 0 票 Disapproval 0	做必要的修正后同意 0 票 Modification required prior to approval 0

	做必要的修正后重审 0 票 Modification required and re-submitted for review 0	终止或暂停试验 0 票 Terminate or suspend its prior approval 0
审查意见 Review recommendation		

根据卫生部《涉及人的生物医学研究伦理审查办法》（2007），SFDA《药物临床试验伦理审查工作指导原则》（2010）、《药物临床试验质量管理规范》（2003）、《医疗器械临床试验规定》（2004）以及 WMA《赫尔辛基宣言》（2008）和 CIOMS《人体生物医学研究国际伦理指南》（2002）的伦理原则，经本医学伦理委员会审查，同意按照所批准的临床研究方案、知情同意书、招募材料等开展本项试验/研究。

According to the World Medical Association Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subject, International Ethical Guidelines for Biomedical Research Involving Human Subjects by the Council for International Organization of Medical Sciences and several Chinese ethical guidelines, the assignment for technical design, informed consent form and case report form were approved by the Research Ethical Committee of Beijing Hospital of Traditional Chinese Medicine affiliated to Capital Medical University.

请遵循 GCP 规定和本伦理委员会批准的方案开展临床研究。
Please carry out the research

该项目进行中如发生下列情况，须及时书面报告本伦理委员会：
The investigator should report to the Ethical Committee if the following occurs:

1）对临床方案、知情同意书等的任何修改；
1) Amendment of research protocol and informed consent form.

2）更换主要研究者；
2) Change of major investigator.

3）发生严重不良事件；
3) Serious adverse events.

4）出现任何可能显著影响试验进行或增加受试者危险的情况；
4) Occurrence of significant influence to the research or increasing harm to participants

5）出现违反方案情况；
5) Deviation of research protocol

6）暂停或提前终止临床研究。
6) Research suspension or termination

本伦理委员会将对该项目跟踪审查，请申请人/申办方按照伦理委员会规定的年度或定期跟踪审查频率，在截止日期前 1 个月提交研究进展报告。

The research ethical committee will track and check the research process according the specified year or frequency, and the research

	progress report should be submitted a month before the deadline. 该项目完成后，请向本伦理委员会提交结题报告。 Please submit research conclusion report to the research ethical committee 如该项目在批件有限期内未能启动临床研究，本批件作废，需要重新提交伦理审查申请。 If the project cannot start within the effective period, this document will be invalid and need resubmitting related documents.
年度/定期跟踪审查频率 Frequency of continuing review	12 个月 12monthes 请于 2018 年 6 月 20 日前提交研究进展报告。 Please submit research progress report before 20 June 2018
批件有效期 Period of validity	2017 年 7 月 21 日-2018 年 7 月 20 日 From 21 July 2017 to 20 July 2018
联系人与联系电话 Responsible person and telephone	田翠 0538-6237875 TianCui 0538-6237875
伦理委员会主任/副主任签字 Research Ethical Committee Director	刘洪霞 LiuHongxia
	山东省泰山医院医学伦理委员会 Research Ethical Committee of Shandong Taishan hospital 日期：2020 年 08 月 17 日 Date：17 August 2020

Research Ethical Committee of Beijing Hospital of Traditional Chinese Medicine affiliated to Capital Medical University

Ethical approval

Approval number: 2017BL-045-01

Research name: **Acupuncture as prophylaxis for chronic migraine: A single-blinded, double-dummy, randomized controlled trial**

Funding: **Beijing Municipal Science & Technology Commission**

Research Institution: **Beijing Hospital of Traditional Chinese Medicine affiliated to Capital Medical University, Beijing, China.**

Investigator: **Bin Li**

Review category: **Review.**

Review procedure: **Meeting Review.**

Review date: **18 July 2017**

Review Institution: **Beijing Hospital of Traditional Chinese Medicine affiliated to Capital Medical University, Beijing, China.**

Approval files:

Assignment for technical design (Version1.0_20170613; Date: 2017/06/13).

Informed consent form (Version1.0_20170613; Date: 2017/06/13).

Case report form (Version1.0_20170613; Date: 2017/06/13).

Headache Diary (Version1.0_20170613; Date: 2017/06/13).

Recruitment material (Version1.0_20170613; Date: 2017/06/13).

Review comment: **Approval 10; Disapproval 0; Modification required prior to approval 0; Modification required and re-submitted for review 0; terminate or suspend its prior approval 0.**

Review recommendation:

The assignment for technical design, informed consent form and case report form were approved by the Research Ethical Committee of Beijing Hospital of Traditional Chinese Medicine affiliated to Capital Medical University according to the World Medical Association Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subject, International Ethical Guidelines for Biomedical Research Involving Human Subjects by the Council for International Organization of Medical Sciences and several Chinese ethical guidelines.

The investigator should report to the Ethical Committee if the following occurs:

1. Amendment of research protocol and informed consent form.

2. Change of major investigator.
3. Serious adverse events.
4. Deviation of research protocol.
5. Research suspension or termination.
6. Occurrence of significant influence to the research or increasing harm to participants.

The frequency of continuing review is determined according to the degree of risk of the research. It will be at least once a year.