

Implementation Process Standardization of International Clinical Trials and Its Application in Chinese Medicine Field

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ABSTRACT The standardized implementation of clinical research is an important guarantee to evaluate the effectiveness of the study protocol. This article is to summarize the organization structure and research process of international clinical trial implementation. Taking *impact of acupuncture combined with clomiphene on polycystic ovarian syndrome anovulation women's live birth: international cooperative randomized controlled trial* (PCOSAct) for example, this article introduces exploration and innovation of standardization implementation in department of gynaecology in First Hospital Affiliated to Heilongjiang University of Chinese Medicine in the process of clinical research of Chinese medicine, by adopting internationalized organizational management model, emphasizing the implementation preparation, emphasizing ethics retrieval and registration update, regular meeting of steering committee, as well as adopting the methods of site inspection and international joint inspection, to provide reference for Chinese medicine clinical research internationalization.

Keywords clinical trial; Chinese medicine; implementation; standardization

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• 同行微评 •

推进中医药临床研究的规范化、国际化

訾明杰

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近年来,从国内外发表的临床研究中,我们欣喜地看到包括针灸在内的中医药临床研究在规范化、国际化的道路上行进的步伐越来越稳健,但在研究设计与实施及质量控制等方面存在的问题也比较多。《国际临床试验规范化实施过程及其在中医药领域的应用》一文结合自身实践经验全面系统地介绍了规范化实施的国际临床试验从伦理审查、数据安全监督委员会的执行到质量控制的细节,值得中医药临床研究者学习和借鉴。对照分析国内的临床试验和国际化的临床试验,主要应从以下方面加以强化:一是研究设计严谨且有临床应用效能。研究设计涵盖的面比较广,研究的最终目的归根结底是要解决临床的问题,让患者有受益。研究设计应围绕这个终极目标进行,同时应有较好的临床可操作性。现有很多的临床研究设计看上去“高大上”,研究结果和结论都很漂亮,但很难与临床实际相结合。二是严格地控制研究质量。研究质量的控制不能仅仅停留在计划以及计划的执行,在临床试验实施流程和管理模式方面需要严格进行过程管理,方能为研究质量提供可靠的保证。三是应注重建立稳定的研究团队,明确的研究方向。优秀的研究成果的发表往往是历经多年、数十人乃至上百人的研究团队分工、分期合作的结果。“快餐”式临床研究很难对临床和学术发展产生深远的影响。

推动中医药临床研究的规范化、国际化进程需要从现在做起,从研究设计到实施的每一个环节做起。期待更多更好更高质量的临床研究结果呈现!