

Project Title: Clinical Study of Liposomal Bupivacaine versus Ropivacaine Hydrochloride for Analgesia Management after Haemorrhoidectomy

Project Category:

- ☐ A. Drug Clinical Trial
- ☐ B. Medical Device Clinical Trial
- ☐ C. New-Technology Application

Name:

Project Institution:      Contact Phone:

Haemorrhoidectomy is a common anorectal surgical procedure associated with severe and prolonged postoperative pain, which carries great clinical significance.

Liposomal bupivacaine injection adopts DepoFoam technology and enables sustained release of bupivacaine for up to 72 hours. It was approved by the FDA in 2011 for wound-infiltration analgesia following haemorrhoidectomy. Although liposomal bupivacaine has been approved for marketing in China in 2024, clinical data regarding its application in anorectal surgery remain limited. No direct head-to-head comparison of efficacy, safety and recovery-related advantages between liposomal bupivacaine and ropivacaine has been performed in haemorrhoidectomy, and high-quality evidence-based data are lacking. It is necessary to fill this evidence gap to optimize analgesic treatment options.

Applicant (Principal Investigator) Undertaking:

If this application is approved, I will conduct the research strictly in accordance with the study protocol and comply with relevant regulations stipulated by the Medical Ethics Committee of Tongliao People's Hospital.

Applicant (Principal Investigator) Signature:

Date: Aug 10, 2026

Ethics Committee Review Opinion:

After review by the Medical Ethics Committee of Tongliao People's Hospital, the applicant meets the qualification requirements. Subjects have been fully informed of detailed study information including their rights, obligations, potential benefits and risks. Measures for protecting subjects' rights and confidentiality are standard. The informed-consent communication approach is reasonable with comprehensive and rigorous content. Upon ethics committee review, this research project has a well-designed protocol. The research content and procedures comply with the national Measures for Ethical Review of Life-Science and Medical Research Involving Human Beings, Implementation Rules for the Regulations on the Administration of Human Genetic Resources, relevant ethical principles and national laws and regulations governing medical ethics.

Seal of the Medical Ethics Committee of Tongliao People's Hospital:

Date: Aug 17, 2026