

上海交通大学医学院附属新华医院医学伦理委员会

Ethics Committee of Xin Hua Hospital Affiliated to Shanghai Jiao Tong University School of Medicine

Approval No.XHEC-D-2020-063

The Ethical Review on the Research of “Focal intrahepatic strictures: diagnosis-treatment experience and a proposal classification”

Di Zhou;Fei Ma;Jiandong Wang;et al have submitted this research proposal entitled “Focal intrahepatic strictures: diagnosis-treatment experience and a proposal classification”. Focal intrahepatic strictures (FIHS) refers to local strictures of the small and medium intrahepatic bile ducts. FIHS is easily misdiagnosed due to its rare incidence and there have been few studies focus on its diagnosis and treatment approaches. Symptoms, results of biochemistry, imaging, endoscopic examinations as well as initial and final diagnosis of 6 patients with FIHS admitted between 2010/01~2019/12 were retrospectively analyzed. The proposed classification system might help to guide diagnosis and treatment for FIHS. Hepatectomy should be performed for not only the malignant FIHS, but also benign strictures with severe secondary damages which is impossible to improve by non-surgical methods. In this study, all patients enrolled in this study has signed the broad consent, which permits the researchers to engage in research use of identifiable biospecimens and identifiable data during the peri-operative period and future follow-up without the requirement to obtain additional consent for the future storage, maintenance, or research uses, so long as the future activities are within the scope of the broad consent. The study protocol as well as the application form were fully reviewed and we have certified that this study did not raise any issues of patient risk or cause any harm to patient. We have also certified that the study was strictly in accordance with the Declaration of Helsinki and International Ethical Guidelines for Health-related Research Involving Humans.

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