Fuzheng Xiaoliu granules reduce the 2-year recurrence rate of early-stage hepatitis B virus-related hepatocellular carcinoma after comprehensive minimally invasive surgery: a study protocol for a prospective, multicenter, central randomized, double-blind, placebo-controlled clinical trial

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Study protocol

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Abstract

Background: Hepatitis B virus (HBV) infection is one of the most common risk factors for hepatocellular carcinoma (HCC). With the continuous improvement of minimally invasive treatment techniques such as transarterial chemoembolization (TACE) and radiofrequency ablation (RFA), comprehensive minimally invasive treatment (TACE & RFA) has been widely used in the treatment of early-stage (Barcelona Clinic Liver Cancer (BCLC) stage 0 and A) HCC and has good safety and clinical efficacy. However, recurrence and metastasis after comprehensive minimally invasive treatment are still key factors affecting the survival rate of patients. In recent years, Chinese medicine has highlighted its unique advantages in the adjuvant treatment of liver cancer surgery and minimally invasive treatment. Thus, this study aimed to evaluate the efficacy and safety of Fuzheng Xiaoliu granules (FZXLG) for treating early-stage HBV-related HCC after comprehensive minimally invasive treatment and to explore whether FZXLG can delay the progression of HBV-related HCC.

Methods: This is a prospective, multicenter, central randomized, double-blind, placebo-controlled clinical trial. A total of 312 patients with early HBV-related HCC who underwent comprehensive minimally invasive treatment within 2 months were randomized in a 1:1 ratio into two groups: the experimental group and the control group. The experimental group will receive basic FZXLG plus Western medicine treatment, and the control group will receive basic FZXLG simulator plus Western medicine treatment. Each group will be treated for 1 year and followed-up for 1 year. The primary outcome measure is the 2-year recurrence rate of patients with early-stage HBV-related HCC after minimally invasive treatment. The secondary outcomes include (1) measurable active lesions, (2) alpha-fetoprotein (AFP), (3) immunological indicators, such as comparison of CD3+, CD4+, CD8+ absolute values, CD4+/CD8+ before and after the test, (4) hepatitis B virus quantity, and (5) Karnofsky functional status score.

Discussion: These results will provide research data on the efficacy and safety of FZXLG for the treatment of early-stage HBV-related HCC after comprehensive minimally invasive treatment. These findings will also be based on laboratory indicators and adverse events for safety assessment to determine whether FZXLG can reduce the 2-year recurrence rate of HCC after minimally invasive surgery, which will provide reliable evidence for the clinical treatment of HCC.

Trial registration: Chinese Clinical Trial Registry, ChiCTR1900022999. Registered on 5 May 2019.

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