STUDY PROTOCOL

Fecal Microbiota Transplantation for Ulcerative Colitis Using Dai and Han Donors

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Ethics Committee: Ethics Committee of the First Affiliated Hospital of Kunming Medical University

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1. BACKGROUND AND RATIONALE

Ulcerative colitis (UC) is a chronic relapsing inflammatory bowel disease characterized by colonic mucosal inflammation. Fecal microbiota transplantation (FMT) has emerged as a promising therapeutic strategy by reconstructing intestinal microbiota. Previous research suggested that FMT using donors from the Dai ethnic group (a minority nationality in Yunnan, China, with special dietary habits) may achieve better clinical outcomes than Han Chinese donors for UC. This study aims to confirm this finding and understand the underlying mechanisms.

The goal is to identify optimal donor characteristics for FMT in UC and uncover mechanisms that may lead to more personalized microbiota therapies.

2. STUDY OBJECTIVES

Primary Objective: To evaluate the clinical efficacy of FMT using healthy Dai donors compared to Han donors in patients with ulcerative colitis.

Secondary Objectives: To compare endoscopic improvement, inflammatory markers, intestinal barrier function, and to identify key gut bacteria and metabolites associated with enhanced efficacy using metabolomics and metagenomics.

3. STUDY DESIGN

This is a randomized, parallel-group, open-label clinical trial conducted at the First Affiliated Hospital of Kunming Medical University. A total of 200 patients with ulcerative colitis will be enrolled and randomly allocated into two groups (n=100 each):

- **Arm 1:** FMT with healthy Han donors (Han Donor FMT Group)
- **Arm 2:** FMT with healthy Dai donors (Dai Donor FMT Group)

Randomization will be performed using a computer-generated randomization sequence. Given the nature of FMT intervention, blinding of participants and care providers is not feasible; however, outcome assessors will be blinded to group allocation where possible.

4. STUDY POPULATION

4.1 Inclusion Criteria

- Age 18–60 years
- Diagnosed with ulcerative colitis (left-sided colitis) according to ECCO guidelines and Chinese Guidelines for the Diagnosis and Treatment of Ulcerative Colitis (2023 Xi'an)
- Baseline Mayo score 3–10
- Treated only with mesalazine before and during the study to exclude drug interference
- Able to provide written informed consent

4.2 Exclusion Criteria

- Pregnancy or planned pregnancy in the near future
- Patients in clinical remission (Mayo score ≤2 with no individual subscore >1)
- Development of diseases different from or confounding the initial diagnosis during the study
- History of toxic megacolon, perianal disease, or intestinal surgery
- Concurrent severe cardiac, pulmonary, or renal disease, or malignancy
- History of autoimmune or allergic diseases, or receiving immunomodulatory therapy
- Infectious diseases (HBV, HCV, syphilis, HIV) or positive stool pathogen testing

4.3 Donor Selection Criteria

Donors will be healthy individuals aged 18–23 years, screened according to AGA guidelines. Dai donors will be recruited from Xishuangbanna, Yunnan; Han donors will be local healthy individuals. All donors will undergo blood and stool infectious pathogen screening within 4 weeks of donation.

5. INTERVENTIONS

Fecal microbiota transplantation will be administered via transendoscopic enteral tubing (TET). Donor stool (60 g) is processed using the CleanFMT method with GenFMTer system, including filtration, centrifugation, washing, and resuspension in sterile normal saline (1.5× volume). The final product is 200 mL fecal suspension.

Dosing Regimen: 60 mL per infusion, administered via TET, once every 3 days, for a total of 3 sessions. Only mesalazine is used before and after FMT to exclude drug interference. Clinical efficacy will be evaluated at 12 weeks post-FMT.

6. OUTCOME MEASURES

6.1 Primary Outcome

Clinical remission at week 12, defined as: Mayo total score ≤2, no individual subscore >1, and endoscopic subscore decreased by ≥1 from baseline (without corticosteroid use).

6.2 Secondary Outcomes

- Mayo score change from baseline
- Mayo Endoscopic Subscore (MES) change
- Histopathological assessment by HE staining
- Fecal calprotectin levels
- C-reactive protein (CRP)
- Erythrocyte sedimentation rate (ESR)

- Intestinal mucosal barrier function
- Metabolomics (LC-MS/MS, GC-MS) and metagenomic sequencing of stool samples at baseline, week 1, and week 12

7. STATISTICAL ANALYSIS

Sample size was calculated based on comparison of clinical remission rates between the two groups. A total of 200 participants (100 per group) provides adequate power to detect a clinically meaningful difference in remission rates. Continuous variables will be compared using t-test or Mann-Whitney U test as appropriate. Categorical variables will be compared using chi-square test or Fisher's exact test. A two-sided p-value <0.05 will be considered statistically significant.

8. ETHICS AND REGULATORY CONSIDERATIONS

This study has been approved by the Ethics Committee of the First Affiliated Hospital of Kunming Medical University (Approval Number: (2026) Ethics Review L No.134-1). All participants will provide written informed consent prior to enrollment. The study will be conducted in accordance with the Declaration of Helsinki and Good Clinical Practice guidelines. This trial is registered on ClinicalTrials.gov (NCT07814456).