

# **The Effect of Intestinal Microbiota Transplantation for Inflammatory Bowel Diseases (IBD)**

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## 1.Method

Intestinal microbiota transplantation(IMT) refers to make fecal from the health into a suspension of microbes through an intelligent bacteria processing system, and then infuse the suspension into the gastrointestinal tract of patients through naso intestinal tube, gastroscope, enteroscope or capsule intake which can reconstruct intestinal microbiota and play the role of treatment without obvious side effect.

## 2.Plan

### 1)Patient recruitment

#### Inclusion Criteria:

- Standard or conventional medicine treatment ineffective of Inflammatory Bowel Diseases(IBM) patients
- IBM patients with recurrent symptoms
- IBM patients who had drug dependence or recurrence when reduced or discontinued use
- Untreated IBM patients who voluntarily received Standardized Intestinal Microbiota Transplantation(IMT)
- Written informed consent/assent as appropriate

#### Exclusion Criteria:

- IBM patients with contraindications for gastrointestinal endoscopy
- IBM patients with indication of surgery
- Moderate and severe renal injury(serum creatinine>2mg/dL or 177mmol/L), moderate and severe chronic obstructive pulmonary disease, severe hypertension, cerebrovascular accident, congestive heart failure, unstable angina pectoris
- Other serious diseases that may interfere the recruitment or affect the survival, such as cancer or acquired immune deficiency syndrome
- Mentally or legally disabled person
- Preparing for pregnancy
- Medical or social condition which in the opinion of the principal investigator would interfere with or prevent regular follow up
- Participating in other clinical trials.

Recruit the patients who meet the inclusion criteria, and fail to meet the exclusion criteria. Introduce this clinical trial to the patients and obtain the informed consent. Assess the condition of the disease.

### 2)Arms and Interventions

Randomly divided the patients into experimental arm and control arm and

intervene them as described in the following table.

arms	Assigned interventions
<p>Experimental: Standardized IMT</p> <p>30 patients with inflammatory bowel disease ongoing traditional drugs will be recruited for the study, which taking intestinal microbiota transplant three times a week.</p> <p>Interventions:</p> <p>Procedure: Intestinal Microbiota Transplantation</p> <p>Procedure: traditional drugs</p>	<p>intestinal microbiota transplant</p> <p>Participants in Experimental group take IMT three times a week.</p> <p>Drug: traditional drugs such as Mesalazine\glucocorticoid, All participants continue his or her therapy.</p>
<p>Traditional drugs</p> <p>30 patients with inflammatory bowel disease ongoing traditional drugs will be recruited for the study</p> <p>Interventions:</p> <p>Procedure: traditional drugs such as Mesalazine\glucocorticoid</p>	<p>Drug: Mesalazine\glucocorticoid</p> <p>All participants continue his or her therapy.</p>

### 3)Outcome Measures

Primary Outcome Measure:

The change of the modified Mayo score

Clinical remission defined as modified Mayo score  $\leq 2$ . Change from baseline will

be assessed at different time point. The endpoint of follow-up is the time of clinical recurrence.

[Time Frame: 1 month, 3 months, 6months, 12 months]

Secondary Outcome Measure:

① The change of CDAI

Clinical remission defined as CDAI (Crohn's disease activity index)  $\leq 150$ . Change from baseline will be assessed at different time point. The

endpoint of follow-up is the time of clinical recurrence.

[Time Frame: 1 month, 3 months, 6months, 12 months]

② Relief of gastrointestinal symptoms

The onset and duration of gastrointestinal symptoms will be assessed by

"Evaluation Score Table of Gastrointestinal Symptoms". Change from

baseline

will be assessed at different time point.

[Time Frame: 1 month, 3 months, 6months, 12 months]

③ Changes of gut microbiota

Alpha and Beta diversity of GI microbiota by High-throughput sequencing

on

baseline line and 1 month, 3 months, 6months, 12 months after treatment.

[Time Frame: 1 month, 3 months, 6months]