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

Date: 2017.05
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 (IBD) patients
   - IBD patients with recurrent symptoms
   - IBD patients who had drug dependence or recurrence when reduced or discontinued use
   - Untreated IBD patients who voluntarily received Standardized Intestinal Microbiota Transplantation (IMT)
   - Written informed consent/assent as appropriate

   Exclusion Criteria:
   - IBD patients with contraindications for gastrointestinal endoscopy
   - IBD 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.

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

3) Outcome Measures

Primary Outcome Measure:

The change of the modified Mayo score

Clinical remission defined as modified Mayo score ≤ 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, 6 months, 12 months]

Secondary Outcome Measure:

1 The change of CDAI

Clinical remission defined as CDAI (Crohn's disease activity index) ≤ 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]