Study on Effect of Intestinal Microbiota Transplantation in Hepatitis B Virus Induced Cirrhosis

Date: 2017-06-28
Study on Effect of Intestinal Microbiota Transplantation in Hepatitis B Virus Induced Cirrhosis

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:
   • Written informed consent/assent as appropriate, able to keep treatment
   • 18 to 50 years of age
   • Chronic hepatitis B, definitely diagnosed as hepatic fibrosis/cirrhosis through Fibroscan/Biopsy of liver biopsy

   Exclusion Criteria:
   • Drug treatment (immunosuppressive drugs, biological agents, high dose vitamins or other immunosuppressive drugs
   • Other immune related diseases
   • Gastrointestinal organic lesions such as gastroesophageal reflux disease, inflammatory bowel disease, intestinal tumor
   • 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: patients with HBV induced cirrhosis</td>
<td>All participants take 4 times IMT by gastroduodenoscopy with 2-week intervals</td>
</tr>
<tr>
<td>patients with HBV induced cirrhosis will be recruited for study, which involved a 4 times intestinal microbiota transplant and the time interval is generally 2 weeks</td>
<td>intestinal microbiota transplant</td>
</tr>
</tbody>
</table>

3) Outcome Measures

Primary Outcome Measure:

1. Fibrosan score of liver fibrosis and steatosis
   [Time Frame: 3 months, 6 months, 12 months]

Secondary Outcome Measure:

2. Symptoms
   The onset and duration of gastrointestinal symptoms will be assessed by "Evaluation Score Table of Gastrointestinal Symptoms".
   [Time Frame: 3 months, 6 months, 12 months]

3. Color Doppler ultrasound of portal vein
   [Time Frame: 3 months, 6 months, 12 months]

4. Changes of gut microbiota
   Alpha and Beta diversity of GI microbiota by High-throughput sequencing (16S rRNA) on baseline line and 1 month, 3 months, 6 months after treatment
   [Time Frame: 1 month, 3 months, 6 months]

5. CT/MRI
   [Time Frame: 3 months, 6 months, 12 months]