

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

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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:

- 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.

arms	Assigned interventions
<p>Experimental: patients with HBV induced cirrhosis</p> <p>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</p>	<p>intestinal microbiota transplant</p> <p>All participants take 4 times IMT by gastroduodenoscopy with 2-week intervals</p>

3) Outcome Measures

Primary Outcome Measure:

- ① Fibroscan score of liver fibrosis and steatosis

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

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, 12months]

- ③ Color Doppler ultrasound of portal vein

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

- 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, 6months after treatment

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

- ⑤ CT/MRI

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