A Clinical Evaluation on Traditional Chinese Medicine Diagnosis and Treatment Program Blocking and Reversing Hepatitis B-related Liver Fibrosis - a Randomized, Controlled, Double-blind, Multi-center Clinical Trial

ClinicalTrials.gov Identifier: NCT01965418

Recruitment Status : Unknown
Verified August 2015 by Beijing 302 Hospital.
Recruitment status was: Recruiting
First Posted : October 18, 2013
Last Update Posted : August 17, 2015

Sponsor:
Beijing 302 Hospital

Information provided by (Responsible Party):
Beijing 302 Hospital

Study Description

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Brief Summary:
This research puts liver biopsy as the enrollment screening criteria and the primary efficacy assessment indicators. Patients at different developmental stages of hepatitis B related liver fibrosis are respectively diagnosed and treated by Traditional Chinese medicine to determine optional diagnosis and treatment

plan of traditional Chinese medicine to screen the advantage-treated population and to establish a treatment program, which can save national medical resources, for clinical application of Traditional Chinese medicine Diagnosis and Treatment blocking and reversing hepatitis B-related liver fibrosis. The research can help to build automation pathological analysis and diagnosis systems and non-invasive clinical assessment criteria and models of liver fibrosis which can be applied in clinical. It can also help to realize electronic patient data collection and management, to establish patients management centre and follow-up database. Then it will help to improve clinical efficacy of being blocked and reversed chronic hepatitis B related liver fibrosis by Chinese medicine Diagnosis and Treatment program, to reduce the incidence of liver cirrhosis and hepatitis B-related mortality, to prolong patients' survival and improve patients' quality of life, to make clinical efficacy, which is about Traditional Chinese Medicine blocking and revering chronic hepatitis B-related liver fibrosis, increase by 15% or more .

Condition or disease	Intervention/treatment	Phase
Liver Fibrosis Chronic Hepatitis B	Drug: Fufang Biejia Ruangan Tablet Drug: Placebo	Phase 4

Study Design

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Study Type :	Interventional (Clinical Trial)
Estimated Enrollment :	1000 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)
Primary Purpose:	Treatment
Study Start Date :	September 2013
Estimated Primary Completion Date :	December 2015

Resource links provided by the National Library of Medicine

MedlinePlus related topics: Hepatitis Hepatitis B

U.S. FDA Resources

Arms and Interventions

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Arm	Intervention/treatment
Active Comparator: Fufang Biejia Ruangan Tablet	Drug: Fufang Biejia

Fufang Biejia Ruangan Tablet will be administered to all of subjects in this arm.	Ruangan Tablet
Placebo Comparator: placebo placebo of Fufang Biejia Ruangan Tablet	Drug: Placebo

Outcome Measures

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Primary Outcome Measures :

1. Liver histological changes [Time Frame: before treatment and after 48 weeks twice]

Eligibility Criteria

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Information from the National Library of Medicine

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:	18 Years to 65 Years (Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

Inclusion criteria of chronic hepatitis B related liver fibrosis:

1. Age from 18 to 65 years old, male or female;
2. Consistent with the diagnosis criteria of chronic hepatitis B;
3. liver fibrosis(liver biopsy) stage F ≥ 3 (Ishak), HBV DNA ≥ 104 copies / ml (or ≥ 2000 IU / ml) were;
4. TCM syndrome type: blood stasis, blood deficiency with toxic heat retention;
5. Not taking over nucleoside antiviral in one year, no drug treatment of liver fibrosis in six

months;

6. Signed informed consent.

Exclusion Criteria:

1. liver fibrosis(Liver biopsy) stage F <3 (Ishak);
2. Combined with other severe chronic hepatitis, cirrhosis, liver cancer and other severe or end-stage liver disease;
3. Accompanied by uncontrollable heart, kidney, lung, endocrine, blood, metabolic and gastrointestinal serious primary disease; or mental illness;
4. Pregnant or lactating women;
5. Patients with allergic constitution or allergic to TCM used;
6. Not be prescribed medication, poor compliance, incomplete data affecting the efficacy and safety of those judgments;
7. Patients unsuitable for this trial in Researchers' consideration;
8. Co-infection with other viral liver disease.

Contacts and Locations

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Information from the National Library of Medicine NIH NLM

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Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT01965418***

Contacts

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Locations

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Sponsors and Collaborators

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More Information

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Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Qu J, Yu Z, Li Q, Chen Y, Xiang D, Tan L, Lei C, Bai W, Li H, Shang Q, Chen L, Hu X, Lu W, Li Z, Chen D, Wang X, Zhang C, Xiao G, Qi X, Chen J, Zhou L, Chen G, Li Y, Zeng Z, Rong G, Dong Z, Chen Y, Lou M, Wang C, Lu Y, Zhang C, Yang Y. Blocking and reversing hepatic fibrosis in patients with chronic hepatitis B treated by traditional Chinese medicine (tablets of biejia ruangan or RGT): study protocol for a randomized controlled trial. Trials. 2014 Nov 10;15:438. doi: 10.1186/1745-6215-15-438.

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Additional relevant MeSH terms:

Hepatitis	Digestive System Diseases
Fibrosis	Pathologic Processes
Hepatitis, Chronic	Hepadnaviridae Infections
Hepatitis B	DNA Virus Infections
Hepatitis B, Chronic	Virus Diseases
Liver Cirrhosis	Hepatitis, Viral, Human
Liver Diseases	