Translation version：

Informed consent form · Informed page

(Version number：Version4.0, version date：Jan 4, 2019)

Dear Sir / Madam：

We will invite you to participate in the special project of the National Key R & D Program "Modernization of Traditional Chinese Medicine"：Clinical study of Yinqi Sanhuang Jiedu Decoction(YQSHD) in the treatment of chronic viral hepatopathy (2018YFC1705700) Neutron topic 2：Clinical study of YQSHD in the treatment of hepatitis B-related compensated liver cirrhosis(LC) (2018YFC1705702), the purpose is to evaluate the effectiveness and safety of YQSHD in the treatment of hepatitis B-related compensated liver cirrhosis and prevention of hepatitis B-related hepatocellular carcinoma (HCC).

Before you decide whether to participate in this study, please read the following as carefully as possible. It can help you understand the study and the reasons for conducting the study, the specific procedures and duration of the study. You will know the benefits and potential discomfort or risks that may be happened when you participating in the study. If you want, you can also discuss with your relatives and friends to help you make decisions.

If you are currently participating in other clinical studies, please inform the researcher.

Research background and research purposes

1. Background

So far, liver cancer is one of the main causes of death in patients with liver disease. In China, the proportion of liver cancer patients caused by HBV infection is about 80%. Traditional Chinese medicine(TCM) shows advantages in the treatment of chronic viral hepatitis B, liver cirrhosis and liver cancer in China. YQSHD is based on the experience of predecessors and combined with clinical practice by Professor Lv Wenliang of Guang'anmen Hospital, Chinese Academy of Chinese Medical Sciences.The combination therapy of TCM and nucleoside analogues to further reduce the incidence of chronic hepatitis B to cirrhosis is urgently needed, at the same time, a high-quality clinical evidence is also needed. Therefore, this study was carried out to combine YQSHD with entecavir(ETV), in the hope that through multi-center, large-sample clinical research, further evaluate the effectiveness and safety of this combination therapy the for hepatitis B-related compensated cirrhosis, and reduce the annual incidence of primary liver cancer in patients with hepatitis B-related compensated cirrhosis .

2. Research purpose

The purpose of this study was to evaluate the effectiveness and safety of YQSHD combined with ETV in the treatment of hepatitis B-related compensated LC, and to reduce the annual incidence of HCC in patients with hepatitis B-related LC.

Qualifications of relevant researchers and research institutions

The main investigator of this study is Chief Physician Lv Wenliang and Liver Disease Prevention Research Team of the Department of Hepatology, Guang'anmen Hospital, Chinese Academy of Chinese Medical Sciences. which with rich clinical experience in treating cirrhosis and liver cancer. The leading unit of this subject is Hangzhou Xixi Hospital, with strong scientific research strength

and strong clinical technical force. This study will be conducted in a total of 5 hospitals in XiXi Hospital of HangZhou (Hangzhou Xixi Hospital Affiliated to Zhejiang University of Traditional Chinese Medicine), ChengDu University of Chinese Medicine Affiliated Hospital, BeiJing ShunYi Traditional Chinese Medicine Hospital, the Sixth People's Hospital of ShenYang, BeiJing DiTan Hospital Capital Medical University.

The number of subjects involved in the study: a total 802 patients will be recruited from 5 centers

People who do not suitable participate this study

(1)Patients with liver cirrhosis caused by other chronic liver diseases;

(2) Acute and chronic hepatitis, autoimmune hepatitis, primary biliary cirrhosis, primary sclerosing cholangitis, hereditary metabolic liver disease, drug or toxic hepatitis, alcoholic Liver disease

(3) Women who are pregnant or breastfeeding and who plan to become pregnant during the study period;

(4) Those allergic to test drugs;

(5) Patients with mental disorders who cannot cooperate with this study, or patients with unstable epilepsy;

(6) Patients with severe heart, brain, lung, kidney, hematopoietic and other system diseases;

(7) There are other observers who are not suitable for drug test observers, or who cannot cooperate with treatment, and it is difficult to make an accurate evaluation of the effectiveness and safety of the drug

(8) Other situations that the researchers think are not suitable for enrollment.

Other alternative treatments

If you do not participate in this study, you are free to choose any other treatment plan that may be beneficial to you. Participating in this study is not the only option for treating this disease. There are many other ways to treat this disease, such as taking entecavir capsules combined with hepatoprotective drugs such as silybin meglumine tablets, diuretics and other conventional western medicine treatment, or taking Chinese patent medicine Yinzhihuang granules, Jiuweigan Capsules, etc.

What to do if you participate in the study

1. Research procedures:

(1) Screening period: All patients will complete the screening test during the screening period to assess whether they meet the inclusion criteria. The screening evaluation includes: the general situation, quantitative observation of symptoms and signs, and corresponding laboratory tests, including: urine pregnancy test (women of childbearing age), hepatitis B five items, HBV DNA, liver function, FibroScan, Liver B-ultrasound or MRI/CT and other examinations.

(2) Treatment period: The treatment period of this study is 52 weeks, you need to be recorded the general situation, observed the symptoms and signs, and conduct the corresponding laboratory examinations at the 26th week ± 14 days, 52 weeks±14 days, which Including: hepatitis B five items, HBV DNA, liver function, etc., and the inspection items include: Alpha-fetoprotein (AFP), liver B ultrasound or MRI/CT and other tests.

(3) Follow-up period: follow-up 52 weeks±4 days after treatment. Follow-up period 26 weeks ±14 days, 52 weeks±14 days to record your general situation, observe symptoms and signs,

and conduct corresponding laboratory tests, including: hepatitis B five items, HBV DNA, liver function, AFP, Examination of liver ultrasound or MRI / CT.

2. The expected duration of participation in the study is about 104 weeks ± 14 days.

3. Treatment plan:

We have two groups and take different treatment therapies. If you meet the inclusion criteria and agree to participate, we will conduct a random grouping. You will have a 50% chance of entering any one of the two groups. You may enter the experimental group takes YQSHD and entecavir dispersible tablets; or you may enter the control group to take placebo and entecavir dispersible tablets. You will conduct a pilot study in the following steps:

If you agree to participate in this study, we will evaluate your eligibility to participate in this study, ask about your health and related diseases history, conduct a relevant physical examination on you, and tell you how to take the medicine.

Test group: taking YQSHD and Entecavir Dispersible Tablets (Chinese traditional medicine granules once in the morning and once in the evening, adding 150 to 200ml of water for 3 to 5 minutes, and entecavir tablets 0.5mg once in the evening. You are suggested taking the medicine on an empty stomach at the same time every day);

Control group: take placebo and entecavir dispersible tablets (Chinese traditional medicine granules placebo once in the morning and once in the evening, adding 150 to 200ml of water for 3 to 5 minutes, and entecavir tablets 0.5mg once in the evening. You are suggested taking the medicine on an empty stomach at the same time every day);

The above drugs need to be taken for 52 weeks.

We will give you 13 weeks of Chinese medicine granules each time. Please contact your research doctor in advance before taking the medicine next time, we will prepare for you in advance. Please return the medicine packaging and medicines that have not been taken every time you visit the researcher again.

We will also send you a medication diary. You need to record each medication in the medication diary. You need to bring the medication diary to the research doctor for review every time you take a medicine. You should return the medication diary to the research doctor at the end of the trial.

4. Stuff requiring your cooperation:

(1) Provide accurate past medical history and current condition information.

(2) Tell the researcher about any health problems that occurred during the study.

(3) During the study period, you should not use other drugs to treat chronic hepatitis B. If you need other treatment, please contact your doctor in advance.

(4) Take the study drug as directed by the doctor and visit as required.

(5) Follow the guidance of researchers and research doctors.

(6) If you have any unclear questions, you can ask at any time.

7. The expected situation and / or reasons for participation in the trial may be terminated;

If there is early termination when in this study, we will notify you in time and the researcher who responsible for you, the doctor will advise you the next treatment plan based on your health.

Expected circumstances and / or reasons that may be terminated;

(1) Poor compliance, irregular medications, and inability to review or review on time;
(2) Some comorbidities, complications, or worsening of the disease occurred during clinical observation;
(3) Those who quit on their own during the test;
(4) Combined medicines, which are not taken according to research regulations;
(5) Contact lost;
(6) Incomplete data, which affect the validity and safety judgment;
(7) Serious adverse reactions occurred during the medication;
(8) In the course of taking the drug, the overall disease worsened and accompanied by obvious adverse reactions;
(9) Those who developed liver cancer during the study;
(10) The study was terminated due to force majeure.

8. Based on the existing experience and test results, speculate that the expected benefits, the risks and inconveniences that may occur of the subjects, and the medical treatment and compensation for research-related injuries;

(1) Expected benefits:

Participating in this clinical study, drug treatment may be beneficial to your disease condition and improve your health.

(2) Possible risks and inconveniences

Possible risks of research drugs: The entecavir dispersible tablets used in this research are all provided by regular manufacturers, and Yinqi Sanhuang Jiedu Tang granules are made in GMP certified pharmaceutical factories. Entecavir dispersible tablets may cause headache, fatigue, dizziness, and nausea. If you experience any discomfort, please contact your attending doctor in timely, we will closely monitor, find the possible reasons in time, and deal with it reasonably.
The risk of the drug to the fetus is unknown, and the two drugs may be dangerous to the fetus. Therefore, we do not recommend pregnant or lactating women to participate in this trial. Female subjects of childbearing age avoid pregnancy during treatment. If you become pregnant while taking study medication, you will not be able to continue participating in this study.

Other potential side effects of combination therapy: there may be risks and deficiencies that we do not know in the treatment, especially if you are applying other drugs while the treatment is going on. For this reason, during treatment, you should avoid using other drugs without first consulting with your research doctor. If a serious adverse event occurs due to the use of other drugs without prior consultation with the research doctor, you should notify your attending doctor in time and bear the adverse consequences caused by it.
During the trial, some other discomfort may occur, please inform the researcher immediately, he / she will deal with your discomfort.

(3) Medical treatment and compensation for research-related harms

If you have an injury that is directly related to the treatment during the trial period, and it is confirmed by the medical appraisal as the injury related to the test drug, the research team will pay your medical expenses or compensation according to your specific situation; For serious adverse events caused by drug-related injuries, the research team will give you a certain amount of

compensation according to relevant national laws and regulations, and the compensation costs will be borne by Guanganmen Hospital.

9. Test cost;

Patients in this study participated voluntarily, and YQSHD granules and placebo used in the treatment process were provided free of charge. Entecavir dispersible tablets are at your own expense. The cost of laboratory tests during the treatment process shall be borne by yourself. There is no compensation for transportation and lost time, and no compensation.

10. Confidentiality of personal information:

Information about your participation in this study will be recorded in the case report form. All research results (including personal data, test documents, etc.) that appear in the original medical records will be completely confidential within the scope allowed by law. Your name will not appear in the case report form, only your name initials and the random number. In relevant research summaries, articles, and public journals, if necessary, only your name initials and number will appear.

When necessary, the drug supervision and administration department, ethics committee, or project funding department may, consult the data of the subjects, of course, they will conduct in accordance with regulations. If without permission, they will not use the subject's information for other purposes or disclose it to other groups.

11. If any information is obtained that may affect the subject's continued participation, the subject or his legal representative will be notified in timely;

During the trial, we may be informed of new information about treatment, and we will notify you in time to let you decide whether to continue to participate in the study or withdraw.

12. How to get more information;

You can ask any questions about this research at any time.

Your attending doctor will leave you his / her phone number so that you can answer your questions.

If any situation happens during the trial that may affect your willingness to continue participating in this study, your doctor will notify you in time.

13. The principle of voluntary participation

At any stage of the trial, you have the right to withdraw from the research at any time without discrimination or retaliation, and its medical treatment and rights are not affected;

Whether to participate in this study depends on your voluntary entirely. You can refuse to participate in this study or withdraw from this study at any time during the study.

Your doctor or researcher may suspend your participation in this trial at any time for your best interests.

If you withdraw from the trial for any reason, you may be consulted about your use of the trial drug. If the doctor thinks it is necessary, you may also be required to undergo laboratory and physical examinations. You also have the right to refuse and will not be discriminated against or retaliated against.

If you choose to participate in this research, we hope that you can continue to complete the

entire research process.

14.Contact information of the Ethics Committee Office,

If you have any complaints, you can contact Ethics Committee Office.

If you have any questions or need to ask someone other than the researcher, please consult the Ethics Committee of Guang'anmen Hospital, China Academy of Chinese Medical Sciences.

Address: Second Floor, Old Outpatient Building, Ethics Committee Office

Tel: 010—88001552 Contact: Miss Qiao

Thank you for reading the above materials. If you decide to participate in this study, please tell your doctor that he / she will arrange all matters related to the study for you.

Please keep this information.

Informed consent form · Signature page

Project Name: Clinical Study of YQSHD in Treating Hepatitis B-related Compensated Liver Cirrhosis

Project funding: National Key R & D Program "Chinese Medicine Modernization Research" key special project

Subject's informed consent statement

I have read the above introduction about this experimental study, and have the opportunity to discuss and ask questions about this study with the reseacher. All the questions I raised were answered satisfactorily.

I understand the possible risks and benefits of participating in this study. I know that participation in the study is voluntary, and I confirm that there is sufficient time to consider this, and I understand:

I have the right to ask the doctor for more information at any time.

I have the right to withdraw from this study at any time without discrimination or retaliation, and medical treatment and rights will not be affected.

I also understand that if I quit halfway due to the drug, I should inform the doctor of the changes in time, which will be very beneficial to me and the entire study.

If I need to take any other treatment due to a change in my condition, I will seek the doctor's advice in advance or tell the doctor truthfully afterwards.

I agree that representatives of the drug supervision and administration department, ethics committee, or project funding department should consult my research materials. I will get a signed and dated copy of the informed consent.

In the end, I decided to agree to participate in this trial and study, and to ensure compliance with medical advice.

Subject's signature: _____ Date: _____

Subject's contact number: _____ Address: _____

Contact person's name: _____ Contact person's phone: _____

Researchers inform statement

I confirm that I have explained the details of the study to the subjects, including their rights and possible benefits and risks, and gave them a copy of the signed informed consent. (The following content is very important, please fill in carefully)

Doctor's signature: _____ Date: _____

Doctor's contact number: _____

Original version：

知情同意书·告知页

（版本号：Version4.0、版本日期：2019.1.4）

尊敬的先生/女士：

我们将邀请您参加国家重点研发计划“中医药现代化研究”专项项目：茵芪三黄解毒汤治疗慢性乙型病毒性肝病的临床研究（2018YFC1705700）中子课题2：茵芪三黄解毒汤治疗乙肝相关性代偿期肝硬化的临床研究（2018YFC1705702），目的在于评价茵芪三黄解毒汤治疗乙肝相关性代偿期肝硬化、预防乙肝相关性肝癌的有效性和安全性。

在您决定是否参加这项研究之前，请尽可能仔细阅读以下内容，它可以帮助您了解本研究以及进行这项研究的原因、研究的具体程序和期限、参加本研究后可能给您带来的益处、风险和不适。如果您愿意，您也可以和您的亲属、朋友一起讨论，帮助您做出决定。

若您目前正参加其他临床研究，请告知您的研究医生或者研究人员。

一、研究背景和研究目的

1、研究背景

迄今为止，肝癌是肝脏疾病患者主要的死亡原因之一。而在我国，肝癌患者中，由HBV感染引起的比例为80%左右。中医药在我国慢性乙型病毒性肝炎、肝硬化及肝癌的治疗中具有独特优势，我们所使用的茵芪三黄解毒汤为中国中医科学院广安门医院肝病科专家在总结前人经验的基础上，结合临床实践，形成的治疗慢性乙型病毒性肝病的经验方，前期预实验显示出较为满意的疗效，故开展本项研究，将茵芪三黄解毒汤与核苷类似物联合应用，以期通过多中心、大样本的临床研究，进一步评价这一治疗方案对乙肝相关性代偿期肝硬化治疗的有效性及安全性，降低乙肝相关性代偿期肝硬化患者原发性肝癌年发生率。

2、研究目的

本研究的目的是评估茵芪三黄解毒汤联合恩替卡韦治疗乙肝相关性代偿期肝硬化，降低乙肝相关性代偿期肝硬化患者原发性肝癌年发生率的有效性与安全性。

二、有关研究者及研究机构资质

本研究的主要研究者是中国中医科学院广安门医院肝病科吕文良主任医师及肝病防治研究团队，临床善于使用中西医结合手段治疗各种急、慢性肝病（各种肝炎、脂肪肝、肝纤维化、肝硬化及肝癌）等,临床经验丰富。本研究承担单位为中国中医科学院广安门医院，为国家中

医药管理局直属三级甲等医院，科研实力强大，临床技术力量雄厚。本研究将在中国中医科学院广安门医院、上海中医药大学附属曙光医院、南昌市第九医院、南京市第二医院、青岛市第六人民医院共5家医院进行。

三、**研究涉及受试者人数**：预计有802名受试者参加本研究，共五家分中心。

四、哪些人不宜参加研究

(1) 其他慢性肝病病因导致的肝硬化患者；

(2) 合并非HBV嗜肝病毒感染的急慢性肝炎、自身免疫性肝炎、原发性胆汁性肝硬化、原发性硬化性胆管炎、遗传代谢性肝病、药物或毒物性肝炎、酒精性肝病患者；

(3) 妊娠或哺乳期妇女以及计划在研究期内妊娠的妇女；

(4) 对试验药物过敏者；

(5) 有精神异常不能配合本研究的患者，或病情不稳定的癫痫病患者；

(6) 合并严重心、脑、肺、肾、造血等系统疾病的患者；

(7) 有其他不宜做药物试验观察者，或不能配合治疗、难以对药物的有效性和安全性做出确切评价者；

(8) 研究者认为不适合入组的其它情况。

5．其他可替代的治疗；如果不参加此研究，您还可以自由选择其他任何本研究之外可能对您有益的治疗方案，参加这个研究不是治疗这个疾病的唯一选择。治疗这个疾病还有其他多种方法可选，如服用恩替卡韦胶囊联合水飞蓟宾葡甲胺片等保肝药、利尿剂等常规西药治疗方案、服用中成药茵栀黄颗粒、九味肝泰胶囊等。

6．如果参加研究将需要做什么

1.研究程序：

（1）筛选期：所有患者将在筛选期完成筛选检查，评估是否符合入选标准。所有病人的筛查评估包括：一般情况的了解，症状及体征的量化观察，并进行相应的实验室检查，包括：尿妊娠试验（育龄期女性）、乙肝五项、HBV DNA、肝功能、甲胎蛋白、上腹部B超或核磁/CT等检查。

（2）治疗期：本研究治疗期为52周，需要在第26周±14天、52周±14天时对您进行一般情况的了解，症状及体征的观察，并进行相应的实验室检查，包括：乙肝五项、HBV DNA、肝功能、甲胎蛋白等，检查项目包括：上腹部B超或核磁/CT等检查。

（3）随访期：治疗结束后随访52周±14天。随访期第26周±14天、52周±14天对您进行一般情况的了解，症状及体征的观察，并进行相应的实验室检查，包括：乙肝五项、HBV

DNA、肝功能、甲胎蛋白、上腹部 B 超或核磁/CT 等检查。

2.参加研究的预期持续时间为 104 周±14 天。

3.治疗方案：

我们一共有两个组别，采取不同的治疗方案，如果您符合入选标准并同意参加，我们将进行随机分组，您将有 50%的可能性进入两组中的任意一组，您有可能进入试验组服用茵芪三黄解毒汤和恩替卡韦分散片，您也有可能进入对照组服用安慰剂和恩替卡韦分散片。您将按以下步骤进行试验研究：

如果您同意参与这项研究，我们将检查您是否符合参加本研究的条件，询问您的健康情况和有关疾病的情况，对您进行相关的体格检查，并告知您服药方法。

试验组：服用茵芪三黄解毒汤和恩替卡韦分散片（中药颗粒剂早晚各一次，加 150 至 200ml 水煎 3 至 5 分钟，饭后半小时服用；恩替卡韦分散片，一日 1 次，每次 0.5mg，每天同一时间空腹服药）；

对照组：服用**安慰剂**和恩替卡韦分散片（中药颗粒剂早晚各一次，加 150 至 200ml 水煎 3 至 5 分钟，饭后半小时服用；恩替卡韦分散片，一日 1 次，每次 0.5mg，每天同一时间空腹服药）；

以上药物均需要服用 52 周。

我们每次将发给您 13 周的中药颗粒剂药量，在下次取药前请提前联系您的研究医生，我们将提前为您做好准备。每次复诊取药时请归还药物外包装及尚未服用的药物。

我们还将发给您一本用药日记，您需要在用药日记上记录每次服药的情况，每次复诊取药时您需要将用药日记带给研究医生进行查看,在研究结束时请将您的用药日记本交还给研究医生。

4.需要您配合的事项：

（1）提供准确的既往病史和当前病情信息。

（2）告诉研究医生您在研究期间出现的任何健康问题。

（3）在研究期间您不可以使用治疗慢性乙型肝炎的其它药物。如您需要进行其它治疗，请事先与您的医生取得联系。

（4）按医嘱服用研究药物，按要求访视。

（5）遵循研究人员和研究医生的指导。

（6）有任何不清楚的地方可以随时询问。

七、参加试验可能被终止的预期情况和/或原因；

如果发生本研究提前终止的情况，我们将及时通知您，您的研究医生会根据您的健康状况为您下一步的治疗计划提供建议。

可能被终止的预期情况和/或原因；

（1）依从性差，服药不规律，不能按时复诊或复查者；

（2）临床观察中发生了某些合并症、并发症，或者病情恶化者；

（3）试验过程中自行退出者；

（4）联合用药，未按研究规定服用者；

（5）失访者；

（6）资料不全，影响有效性和安全性判断者；

（7）服药过程中，出现大量严重不良反应者；

（8）服药过程中，出现整体疾病恶化，并伴随明显不良反应者；

（9）在研究过程中发生肝癌者；

（10）研究因不可抗因素中止。

八、根据已有的经验和试验结果推测受试者预期可能的受益，可能发生的风险与不便，以及出现与研究相关损伤的医疗与补偿；

（1）**预期可能的受益**：参加本项临床研究，药物治疗可能对您的病情有益，您的病情可能得到改善。

（2）**可能发生的风险与不便**

使用研究药物可能的风险：本研究所用的恩替卡韦分散片均由正规厂家提供，茵芪三黄解毒汤颗粒剂在经 GMP 认证的药厂制成。服用恩替卡韦分散片可能会出现头痛、疲劳、眩晕、恶心。如您出现任何不适，请及时与您的主治医生联系，我们会严密监测，及时发现，合理处理。

药物对于胎儿的风险是未知的，并且两种药物可能对于胎儿是危险的，因此，我们不建议妊娠或哺乳期妇女参加本临床试验，育龄女性受试者在治疗期间避免妊娠。若在服用研究药物期间妊娠，将不能继续参加本研究。

联合治疗存在出现其他副反应的可能性：治疗中可能出现我们未知的风险和缺陷，尤其是您在治疗进行的同时还应用其他的药物。基于此原因，在治疗期间，未经事先与您的研究医生商议，您应避免使用其他的药物。如因事先未与研究医生商议，自行使用其他药物导致发生严重不良事件，您应该及时通知您的研究医生，并自行承担由此造成的不良后果。

在试验期间，也许会出现其他一些不适，请立即告知您的研究医生，他/她会对您出现

的不适进行处理。

（3）**出现与研究相关损伤的医疗与补偿**

如果您在治疗过程中发生了直接与本研究明确有关的损伤，经医疗鉴定证实是试验药物相关损伤时，将根据您的具体情况，课题组将支付您的医疗费用或赔偿；如发生与试验药物引起的相关损伤导致的严重不良事件，课题组将按国家有关法律法规给予您一定的补偿，赔偿费用由广安门医院承担。

九、试验费用；

本研究患者自愿参加，治疗过程中使用的茵芪三黄解毒汤颗粒剂和安慰剂免费提供。恩替卡韦分散片需自行负担。治疗过程中的化验检验费用需自行负担。不设交通费及误工费等补偿，不设报酬。

十、个人信息保密问题：

您参加本项研究的信息均会记录在病例报告表中。所有出现在原始医学记录中的研究结果（包括个人资料、化验单据等）均会在法律允许范围内完全保密。您的名字不会出现在病例报告表中，仅仅出现您的姓名拼音缩写和您参加试验时分配的编号。相关研究总结、文章、公开刊物中，如有必要，也仅会出现您的姓名拼音缩写和编号。

必要时，药品监督管理部门、伦理委员会或课题资助部门，按规定可以查阅受试者资料。但未经允许，他们不会将受试者资料用于其他的用途或泄露给其他的团体。

十一、如果得到可能影响受试者继续参加试验的信息，受试者或其合法代理人将及时得到通报；

在试验过程中我们可能会获知有关治疗的新信息，我们会及时通知您，让您决定是否继续参加研究或退出。

十二、 怎样获得更多的信息；

您可以在任何时间提出有关本项研究的任何问题。

您的医生将给您留下他/她的电话号码以便能回答您的问题。

如果在试验过程中出现任何可能影响您继续参加本研究意愿的重要新信息时，您的医生将会及时通知您。

十三、自愿参与研究的原则，在试验的任何阶段有随时退出研究并且不会遭到歧视或报复，其医疗待遇与权益不受影响的权力；

是否参加本研究完全取决于您的自愿。您可以拒绝参加此项研究，或在研究过程中的任何时间退出本研究。

您的医生或研究者出于对您的最大利益考虑，可能会随时中止您参加本项试验。

如果您因为任何原因从试验中退出，您可能被咨询有关您使用试验药物的情况。如果医生认为需要，您也可能被要求进行实验室检查和体格检查。您也有权选择拒绝，并不会因此受到歧视或报复。

如果您选择参加本项研究，我们希望您能够坚持完成全部研究过程。

十四、伦理委员会办公室联系方式，如有抱怨，可与之联系。

如果您有疑问或需要向除研究者以外的人员询问,请咨询中国中医科学院广安门医院伦理委员会。

伦理委员会办公室：中国中医科学院广安门医院老门诊楼二楼伦理委员会办公室

联系电话：010—88001552　　联系人：乔老师

感谢您阅读以上材料。如果您决定参加本项研究，请告诉您的医生，他/她会为您安排一切有关研究的事务。

请您保留这份资料。

知情同意书·同意签字页

项目名称：茵芮三黄解毒汤治疗乙肝相关性代偿期肝硬化的临床研究
项目来源：国家重点研发计划“中医药现代化研究”重点专项

受试者知情同意声明

我已经阅读了上述有关本试验研究的介绍，而且有机会就此项研究与医生讨论并提出问题。我提出的所有问题都得到了满意的答复。

我了解参加本研究可能产生的风险和受益。我知晓参加研究是自愿的，我确认已有充足时间对此进行考虑，而且明白：

我有权随时向医生咨询更多的信息。

我有权随时退出本研究，而不会受到歧视或报复，医疗待遇与权益不会受到影响。

我同样明白，如果我因本药物的原因而中途退出，我应及时将病情变化告诉医生，这将对我本人和整个研究十分有利。

如果我因病情变化需要采取任何其他的治疗，我会事先征求医生的意见，或在事后如实告诉医生。

我同意药品监督管理部门、伦理委员会或课题资助部门代表查阅我的研究资料。我将获得一份经过签名并注明日期的知情同意书副本。

最后，我决定同意参加本项试验研究，并保证遵从医嘱。**（以下内容非常重要，另请认真填写）**

受试者签名：_____ 日期：_____年_____月_日

受试者联系电话：_____ 住址：_____

联系人姓名：_____ 联系人电话：_____

研究者告知声明

我确认已向受试者解释了本研究的详细情况，包括其权利以及可能的受益和风险，并给其一份签署过的知情同意书副本。

医生签名：_____　　日期：_____年_____月_____日

医生联系电话：_____