

# Controlled study of hepatitis B virus level alteration in hepatocellular carcinoma while treating with transcatheter arterial chemoembolisation alone or in combination with interferon-alpha

<b>Submission date</b> 10/01/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 15/05/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 15/05/2009	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Maoquan Li

**Contact details**  
Interventional Department  
Affiliated 10th People's Hospital of Tongji University  
No. 301 Middle Yanchang Road  
Shanghai  
China  
200072  
cjr.limaoquan@vip.163.com

## Additional identifiers

**Protocol serial number**  
N/A

# Study information

## Scientific Title

Controlled study of hepatitis B virus level alteration in hepatocellular carcinoma: monotherapy with transcatheter arterial chemoembolisation versus double therapy with transcatheter arterial chemoembolisation and interferon-alpha: a randomised controlled trial

## Study objectives

Hepatitis B virus (HBV) has been proved as one principal inducer of hepatocellular carcinoma (HCC) by epidemiology study and animal experiment. And for many unresectable HCC, transcatheter arterial chemoembolism (TACE) is the most effective way to relieve the disease and elongate life. However, some studies have revealed that TACE may reactivate HBV replication and result in worse prognosis in HCC patients.

Some evidences show that interferon-alpha (IFN-a) can reduce HBV level effectively and safely. In addition, IFN-a has also been proved a worthwhile therapy to HBV-related HCC with postponed recurrence and prolonged life time. We assume that at the same time of TACE treatment, administration of IFN-a may suppress the reactivation of HBV replication. To test our assumption, we designed a randomised controlled study in HCC patients with positive hepatitis B surface antigen (HBs-Ag) and hepatitis B e antigen (HBe-Ag) to evaluate the efficacy of HBV inhibition and survival by double therapy with TACE and IFN-a versus monotherapy with TACE.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethics Committee of the Affiliated 10th People's Hospital, Tongji University, approved in October 2008 (ref: 08-10-5).

## Study design

Randomised controlled non-blinded single-centre study

## Primary study design

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Hepatitis B virus related hepatocellular carcinoma

## Interventions

All included patients will be divided into two groups by randomisation. One group will receive double therapy with TACE and IFN-a, while the other group will receive monotherapy with TACE as control.

A 0.2% emulsion of epirubicin mixed with lipiodine (GUERBET™) is used for TACE in both groups. IFN-a is administered at a dosage of 60 ug every other day for a duration of 6 months. The

frequency and total duration of TACE therapy for each group is once per month and 3 times in total. Follow-up for HBV-DNA level, survival and progress free survival (PFS) will last for 6 months.

### **Intervention Type**

Other

### **Phase**

Phase IV

### **Primary outcome(s)**

1. HBV reactivation, defined as a greater than 10-fold increase in serum HBV-DNA compared with the baseline level
2. Hepatitis due to HBV reactivation, defined as a threefold or greater increase in serum ALT to a level that exceeded 100 IU/L (reference range less than 33 IU/L) in patients with HBV reactivation in the absence of clinical features of tumour progression, hepatotoxic drugs, treatment-related hepatic damage, or other systemic infections
3. Disease progress, according to the Response Evaluation Criteria in Solid Tumors (RECIST) standard
4. Patient death

The outcomes above will be measured every month after the end of therapy until 6 months.

### **Key secondary outcome(s)**

Severe complications: unendurable fever, hepatic decompensation, measured every month after the end of therapy until 6 months.

### **Completion date**

01/09/2009

## **Eligibility**

### **Key inclusion criteria**

1. Image or pathologically diagnosed HCC
2. Newly diagnosed HCC
3. Unresectable HCC
4. Positive serum HBS-Ag and HBe-Ag
5. Child-Pugh scale A and B
6. Older than 20 years, either sex
7. Patients without jaundice

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

**Sex**

All

**Key exclusion criteria**

1. Previous history of antiviral therapy
2. Baseline serum alanine aminotransferase (ALT) level 2.5 times the upper limit of normal or higher
3. Serum HBV DNA level greater than 107 copies/mL
4. Main portal vein thrombosis
5. Underlying cardiac or renal diseases
6. Positive tests for antibody to hepatitis C virus or human immunodeficiency virus
7. ChildPugh classification C
8. Pre-existing evidence of hepatic decompensation

**Date of first enrolment**

01/12/2008

**Date of final enrolment**

01/09/2009

**Locations****Countries of recruitment**

China

**Study participating centre****Interventional Department**

Shanghai

China

200072

**Sponsor information****Organisation**

Affiliated 10th People's Hospital of Tongji University (China)

**ROR**

<https://ror.org/03vjkf643>

**Funder(s)****Funder type**

Hospital/treatment centre

**Funder Name**  
Affiliated 10th People's Hospital of Tongji University (China)

## Results and Publications

Individual participant data (IPD) sharing plan

**IPD sharing plan summary**  
Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes