

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

Submission date 10/01/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 15/05/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 15/05/2009	Condition category 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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 worthful 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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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.

Secondary outcome measures

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

Overall study start date

01/12/2008

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

Age group

Adult

Sex

Both

Target number of participants

116

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)

Sponsor details

No. 301 Middle Yanchang Road
Shanghai
China
200072

Sponsor type

Hospital/treatment centre

Website

<http://www.shdsyy.com.cn>

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration