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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	[ ] Prospectively registered [ ] Protocol
Registration date 15/05/2009	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 15/05/2009	**Condition category** Cancer	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 hepatiocellular 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

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