

Effect of an emerging treatment for liver cancer

Submission date 29/06/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 08/07/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 05/07/2024	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Transarterial chemoembolisation (TACE) is a cancer treatment where small particles are injected into the blood vessel that feeds the tumour to block off the blood supply. This study aimed to compare the effectiveness and safety of transarterial chemoembolization with CalliSpheres® drug-eluting beads loading with doxorubicin (DEB-TACE) versus conventional lipiodol (cTACE) in patients with unresectable hepatocellular carcinoma (HCC, a liver tumor that can't be removed with surgery).

Who can participate?

Patients aged 18-65 years with unresectable hepatocellular carcinoma (HCC)

What does the study involve?

Participants are randomly assigned to either the DEB-TACE group or the conventional lipiodol (cTACE) group. The DEB-TACE group received CalliSpheres® microspheres loaded with doxorubicin injected into the hepatic artery. The cTACE group received lipiodol combined with doxorubicin injected into the hepatic artery. All patients underwent baseline assessment, including clinical examination, laboratory tests, imaging studies, and liver function tests at the start of the study and after 3 and 12 months.

What are the possible benefits and risks of participating?

Tumor morphology on baseline imaging could inform decisions on the type of TACE that the individual patient would benefit from the most.

Where is the study run from?

Beijing Youan Hospital Capital Medical University (China)

When is the study starting and how long is it expected to run for?

January 2021 to December 2022

Who is funding the study?

You An Union Fund for liver disease and infectious disease (LM202005) (China)

Who is the main contact?

Guangming Li, lign_light@163.com

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

Efficacy of CalliSpheres® drug-loaded microspheres combined with doxorubicin in hepatocellular carcinoma

Study objectives

Tumor morphology on baseline imaging could inform decisions on the type of transarterial chemoembolization (TACE) that the individual patient would benefit from the most. Further studies are needed to confirm and elucidate these findings and to compare CalliSpheres® drug-eluting beads loading with doxorubicin (DEB-TACE) with other types of TACE.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 08/04/2021, Ethics Committee of Beijing Youan Hospital Capital Medical University (No.8 You'anmenwai Xitoutiao, Beijing, 100000, China; +86 (0)1083997028; bjyouanyiyuan@163.com), ref: LL-2021-035-K

Study design

Single-centre interventional randomized controlled trial

Primary study design

Interventional

Study type(s)

Treatment, Efficacy

Health condition(s) or problem(s) studied

Hepatocellular carcinoma (HCC)

Interventions

A total of 144 patients were randomly assigned to either the DEB-TACE group or the conventional lipiodol (cTACE) group using a computer-generated randomization sequence. The allocation ratio was 1:1. The patients, investigators, and outcome assessors were unaware of the group allocation.

DEB-TACE group received CalliSpheres® microspheres (CSM) loaded with doxorubicin via a transarterial approach. The CSM were prepared by mixing poly lactic-co-glycolic acid (PLGA) microspheres with doxorubicin in a ratio of 1:10 in phosphate-buffered saline solution. The CSM were then injected into the hepatic artery under fluoroscopic guidance using a catheter system. The dose of doxorubicin was 20 mg per session, which was considered the maximum tolerated dose based on previous studies. cTACE group received lipiodol combined with doxorubicin via a transarterial approach. The lipiodol was prepared by mixing with doxorubicin of 20 mg per session and then injected into the hepatic artery under fluoroscopic guidance using a catheter system.

All patients underwent baseline assessment, including clinical examination, laboratory tests, imaging studies, and liver function tests at baseline and after 3 months and 12 months follow-up.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

CalliSpheres® drug-eluting beads loaded with doxorubicin (DEB-TACE) or conventional lipiodol (cTACE)

Primary outcome(s)

1. Serum AFP level measured by enzyme-linked immunosorbent assay at baseline and after 3 months and 12 months follow-up
2. Tumor morphology measured using multidetector computed tomography (MDCT) or magnetic resonance imaging (MRI) evaluation at baseline and after 3 months and 12 months follow-up

Key secondary outcome(s)

There are no secondary outcome measures

Completion date

31/12/2022

Eligibility

Key inclusion criteria

1. Histologically confirmed diagnosis of HCC
2. No previous treatment for HCC
3. No contraindications for surgery, liver transplantation, or local ablation
4. No previous treatment with chemotherapy or targeted therapy for HCC
5. No history of radiation therapy for HCC
6. No history of radioembolization for HCC
7. No history of radiofrequency ablation for HCC
8. No history of percutaneous ethanol injection for HCC

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

65 years

Sex

All

Total final enrolment

144

Key exclusion criteria

Patients who had received any of the above treatments within 6 months before enrollment

Date of first enrolment

09/04/2021

Date of final enrolment

01/06/2021

Locations

Countries of recruitment

China

Study participating centre
Beijing Youan Hospital Capital Medical University
No.8 You'anmenwai Xitoutiao
Beijing
China
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Sponsor information

Organisation
Beijing YouAn Hospital

ROR
<https://ror.org/04etaja30>

Funder(s)

Funder type
Research organisation

Funder Name
You An Union Fund for liver disease and infectious disease

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Guangming Li (lign_light@163.com).

IPD sharing plan summary

Available on request