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Effect of an emerging treatment for liver cancer

Submission date
29/06/2024

Recruitment status
No longer recruiting

Registration date
08/07/2024

Overall study status
Completed

Last Edited
05/07/2024

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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, ligm_light@163.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment, Efficacy

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet.

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

Pharmaceutical study type(s)
Pharmacodynamic

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
CalliSpheres® drug-eluting beads loaded with doxorubicin (DEB-TACE) or conventional lipiodol (cTACE)

Primary outcome measure
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

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/01/2021

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
200

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
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Sponsor information

Organisation
Beijing YouAn Hospital

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.bjyah.com

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

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
31/07/2024

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 (ligm_light@163.com).

IPD sharing plan summary
Available on request