ISRCTN12249513 https://doi.org/10.1186/ISRCTN12249513

A study to evaluate the adjuvant pattern in resected intermediate-stage hepatocellular carcinoma

Submission date
24/03/2025

Recruitment status
No longer recruiting

Registration date
16/06/2025

Overall study status
Completed

Last Edited
11/06/2025

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
Intermediate-stage hepatocellular carcinoma (HCC) following curative liver resection (LR) is associated with high recurrence rates and poor survival outcomes. This study evaluates the benefit of transarterial chemoembolization (TACE) combined with Lenvatinib plus programmed death-1 inhibitors (TAP) as an adjuvant treatment for resected intermediate-stage HCC compared to TACE alone. This study aims to (1) compare the efficacy of TACE-Lenvatinib-Programmed Death-1 inhibitors (TAP) versus TACE alone as adjuvant therapy for resected intermediate-stage HCC, and (2) identify subgroups most likely to benefit from TAP using predictive risk modeling.

Who can participate?
Patients with intermediate-stage HCC who underwent LR

What does the study involve?
Data were collected from the medical records of patients with intermediate-stage HCC who underwent LR. Overall survival (OS) and disease-free survival (DFS) were compared between patients with TACE and TAP using propensity score matching. Subgroup analyses were performed to present the intervention effects. The 2-year recurrence rate in the entire cohort was predicted based on the TACE group, and the interaction between the predicted DFS risk and observed DFS was tested.

What are the possible benefits and risks of participating?
No benefits or risks provided at registration

Where is the study run from?
West China Hospital, Sichuan University, China

When is the study starting and how long is it expected to run for?
January 2024 to October 2025

Who is funding the study?
1. The National Natural Science Foundation of China
2. The Sichuan Science and Technology Program
3. Postdoctoral Research Fund of West China Hospital, Sichuan University

Who is the main contact?
Guanhua Chen, 2839674774@qq.com

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Guanhua Chen

Contact details
West China Hospital of Sichuan University
Chengdu City, Sichuan Province
China
610041
+86 19960597910
G.H.Chen769@look.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
2024-189, 81770566, 82400708, 2023YFS0229, 2025ZNSFSC1683, 2024HXBH112

Study information

Scientific Title
Triple adjuvant therapy with TACE, lenvatinib, and PD-1 inhibitors improves short-term recurrence control in high-risk patients with resected intermediate-stage hepatocellular carcinoma

Acronym
TAP-RISHCC

Study objectives
Transarterial chemoembolization combined with antiangiogenic therapy (lenvatinib) plus programmed death-1 inhibitors (TAP) shows better overall survival and disease-free survival in intermediate-stage HCC.

Primary objective:
A single-centre retrospective cohort study to evaluate the Benefit of Transarterial Chemoembolization (TACE) combined with antiangiogenic therapy (Lenvatinib) plus

Programmed Death-1 Inhibitors (TAP) as an Adjuvant Treatment for resected Intermediate-Stage Hepatocellular Carcinoma.

Secondary objectives:
1. To evaluate the benefit of the combination of TACE and Lenvatinib plus different programmed death-1 inhibitors in resected Intermediate-Stage Hepatocellular Carcinoma
2. Subgroup analysis to evaluate the response to TAP pattern in resected Intermediate-Stage Hepatocellular Carcinoma
3. Comparison of the effectiveness of TACE and TAP on tumor recurrence
4. Evaluate the safety of the TAP therapy

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 10/01/2024, Biomedical Ethics Review Committee of the West China Hospital, Sichuan University (No.37, Guoxue Alley, Wuhou District, Chengdu, Sichuan Province, 610000, China; +86 28 8542 2581; hxlcyjglb@163.com), ref: 20140110189

Primary study design
Observational

Study design
Single-centre retrospective cohort study

Study type(s)
Treatment, Efficacy

Health condition(s) or problem(s) studied
Adjuvant therapy in intermediate-stage hepatocellular carcinoma

Interventions
This single-centre retrospective cohort study aims to evaluate the effectiveness of TACE combined with Lenvatinib plus Programmed Death-1 Inhibitors therapy in patients with intermediate-stage HCC who underwent liver resection compared to TACE alone
Control group: TACE group
Description: Patients who underwent liver resection receive TACE after 4-6 weeks when the liver function has recovered.
Intervention group: TACE+ Lenvatinib+ Programmed Death-1 Inhibitors (drug)
Description: Patients who underwent liver resection receive an adjuvant regimen involving TACE, Lenvatinib and Programmed Death-1 Inhibitors. The programmed Death-1 Inhibitors include Sintilimab, Camrelizumab, Tislelizumab and Pembrolizumab.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Lenvatinib, sintilimab, camrelizumab, tislelizumab, pembrolizumab

Primary outcome(s)
Disease-Free Survival (RFS), defined as the time from the date of curative resection to the date at which HCC recurred, measured using retrospective patient data at one timepoint

Key secondary outcome(s)
The following secondary outcome measures were assessed using retrospective patient data at one timepoint:
1. Overall survival, defined as the period from the time of surgery to the point of death due to hepatocellular carcinoma
2. Safety in patients who received TAP treatment according to National Cancer Institute Common Toxicity Criteria Adverse Events (CTCAE) version 5.0

Completion date
03/10/2025

Eligibility

Key inclusion criteria
1. Patients with intermediate-stage HCC undergoing curative LR.
2. Patients who received TACE alone or Lenvatinib+ PD-1 inhibitors +TACE
3. Child-Pugh class A or B that could improve to class A after treatment

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
571

Key exclusion criteria
1. Patients who received any other adjuvant protocols
2. Without complete clinical data
3. Lost to Follow-up
4. Patients who died within three months post-surgery
5. A history of other malignancies or recurrent HCC.

Date of first enrolment
08/05/2024

Date of final enrolment
02/10/2024

Locations

Countries of recruitment
China

Study participating centre
West China Hospital
-
Chengdu, Sichuan Province
China
610000

Sponsor information

Organisation
West China Hospital of Sichuan University

ROR
https://ror.org/007mrxy13

Funder(s)

Funder type
Government

Funder Name
National Natural Science Foundation of China

Alternative Name(s)
Chinese National Science Foundation, Natural Science Foundation of China, National Science Foundation of China, NNSF of China, NSF of China, National Nature Science Foundation of China, Guójiā Zìrán Kēxué Jījīn Wěiyuánhuì, , NSFC, NNSF, NNSFC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
China

Funder Name
Sichuan Provincial Science and Technology Support Program

Alternative Name(s)
Science and Technology Project of Sichuan, Sichuan Province Science and Technology Support Program, Science and Technology Project of Sichuan Province

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
China

Funder Name
West China Hospital, Sichuan University

Alternative Name(s)
West China Hospital, West China School of Medicine and West China Hospital, Sichuan University, WCH, WCSM/WCH

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
China

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated will be available upon request from Guanhua Chen, G.H. Chen769@outloom.com

IPD sharing plan summary
Available on request