

Mutations with survival and recurrence in resected liver cancer

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| Submission date 15/01/2023 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 30/01/2023 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 30/01/2023 | 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

Intrahepatic cholangiocarcinoma (ICC) is the second most common primary liver cancer and characterized by high invasiveness and frequent postoperative recurrence. In view of high tumor recurrence, adjuvant strategies have been explored for many years. We are in urgent need of biomarkers to better select which patients are more likely to benefit from adjuvant chemotherapy.

Who can participate?

Patients with resected ICC

What does the study involve?

We enrolled patients with primary ICC from August 2014 to July 2019 who received curative resection in the Department of Liver Surgical Oncology of Zhongshan Hospital, Fudan University, Shanghai, China, and collected tissue samples from their tumors and matched non-cancerous livers. A part of each frozen sample was subjected to whole-exome sequencing. Some frozen samples and formalin-fixed, paraffin-embedded samples were used for Sanger sequencing.

What are the possible benefits and risks of participating?

This research aims to discover new biomarkers that will help to select patients who are more likely to benefit from adjuvant chemotherapy. There were no risks of participating.

Where is the study run from?

Zhongshan Hospital, Fudan University (China)

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

January 2014 to September 2022

Who is funding the study?

1. National Natural Science Foundation of China (No. 82173260, No. 81972708, No. 82072681, No. 82003082)
2. Shanghai Technical Standard Program (21DZ2201100)
3. Shanghai Medical Innovation Research Project (22Y11907300)

Who is the main contact?
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Contact information

Type(s)

Principal investigator

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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

Association of IDH1 mutations with survival and recurrence in resected intrahepatic cholangiocarcinoma received or not received adjuvant chemotherapy

Study objectives

The presence of IDH1 mutations was associated with better survival and decreased risk of recurrence in patients with resected ICC who received adjuvant chemotherapy

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 06/05/2021, Research Ethics Committee of Zhongshan Hospital (Zhongshan Hospital, Fudan University, 136 Yi Xue Yuan Road, Shanghai 200032, China; +86-21-31587871; ec@zs-hospital.sh.cn), ref: B2021-305

Study design

Single-centre cohort study

Primary study design

Observational

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Intrahepatic cholangiocarcinoma

Interventions

Our research is an observation study. No intervention was involved in the course of the study. We collected tissue samples from patients attending the Department of Pathology of Zhongshan Hospital. The team enrolled patients with primary ICC who were receiving curative resection. Tissue samples were collected from the tumors and matched non-cancerous livers. All the tissues were used for whole-exome sequencing or Sanger sequencing to discover biomarkers to better select which patients are more likely to benefit from adjuvant chemotherapy. The clinical information of patients about treatment methods and survival time were collected from the clinical information database of Zhongshan Hospital. Before surgical operation and tissue sample collection, oral and written informed consent from each participant, with information such as the use of tissue sample and clinical characteristics for scientific research, which was granted by The Research Ethics Committee of Zhongshan Hospital. Patients receiving palliative surgeries, prior interventions or who have other primary malignancies and inflammatory diseases during the follow-up were excluded from the study. Patients who received chemotherapy or not received adjuvant chemotherapy after surgery.

Intervention Type

Procedure/Surgery

Primary outcome(s)

1. Disease-free survival (DFS), defined as the interval between the surgery and any diagnosis of recurrence, measured using data collected every 3 months in the clinical information database of Zhongshan Hospital at one timepoint
2. Overall survival (OS), defined as the time from the date of surgery until death or to the end of follow-up, measured using data collected every 3 months in the clinical information database of Zhongshan Hospital at one timepoint

Key secondary outcome(s)

Gene mutation measured using whole-exome sequencing or Sanger sequencing at one timepoint

Completion date

30/09/2022

Eligibility

Key inclusion criteria

1. Age >20 years old
2. Male/female
3. Primary Intrahepatic Cholangiocarcinoma in patients who received curative resection

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

803

Key exclusion criteria

1. Patients receiving palliative surgeries, prior interventions or with other primary malignancies and inflammatory diseases during the follow-up were excluded from the study
2. Patients with further lymph node involvement were considered to have distant metastasis and were excluded from the study.

Date of first enrolment

01/01/2021

Date of final enrolment

01/09/2022

Locations

Countries of recruitment

China

Study participating centre

Zhongshan Hospital, Fudan University

1609 Xie Tu Road

Shanghai

China

200032

Sponsor information

Organisation

Zhongshan Hospital

ROR

<https://ror.org/032x22645>

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 Wěiyuánhùi, , NSFC, NNSF, NNSFC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

China

Funder Name

Shanghai Technical Standard Program

Funder Name

Shanghai Medical Innovation Research Project

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be published as a supplement to the results publication.

IPD sharing plan summary

Published as a supplement to the results publication