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Mutations with survival and recurrence in resected liver cancer

Submission date 15/01/2023	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 30/01/2023	**Overall study status** Completed	
Last Edited 30/01/2023	**Condition category** Cancer	

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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Cohort study

Study setting(s)
Hospital, Laboratory, Medical and other records

Study type(s)
Diagnostic

Participant information sheet
No participant information sheet available

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 measure
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

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

Overall study start date
01/01/2014

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

Age group
Adult

Sex
Both

Target number of participants
803

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

Sponsor details
Fudan University
1609 Xie Tu Road
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200032
+86 21 64041990
ec@zs-hospital.sh.cn

Sponsor type
Hospital/treatment centre

Website
http://www.zs-hospital.sh.cn/e/intro/

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 Wěiyuánhuì, 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

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

Intention to publish date
01/01/2024

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