ISRCTN12021668 https://doi.org/10.1186/ISRCTN12021668

The influence of body composition on liver cancer patients undergoing surgery

Submission date	Recruitment status	[_] Prospectively registered
30/04/2024	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/05/2024	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
09/06/2025	Cancer	

Plain English summary of protocol

Background and study aims
Stage I/II hepatocellular carcinoma (HCC) is early-stage liver cancer that is localized to the liver and has not spread to other parts of the body. The effect of body composition on stage I/II HCC after surgery is unknown. This study aimed to investigate the impact of low skeletal muscle bulk and disturbed body fat mass on cancer recurrence in stage I/II HCC patients undergoing liver surgery.

Who can participate?
1. From 2012 to 2021, all stage I and II HCC patients aged between 18 and 90 years old who received curative liver surgery by the same surgical team at Linkou Chang Gung Memorial Hospital
2. Healthy adults aged less than 55 years who had abdominal CT scans

What does the study involve?
Body composition including skeletal muscle mass and body fat volume was measured before surgery with computed tomography (CT scans) in patients with HCC. HCC recurrence outcome was recorded and analyzed. The body composition of healthy adults was also measured with CT scans.

What are the possible benefits and risks of participating?
There are no side effects from participating in the study.

Where is the study run from?
Linkou Chang Gung Memorial Hospital (UK)

When is the study starting and how long is it expected to run for?
February 2021 to July 2023

Who is funding the study?
Linkou Chang Gung Memorial Hospital (UK)

Who is the main contact?
Chao-Wei Lee, alanchaoweilee@hotmail.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Prof Chao-Wei Lee

Contact details
No. 5, Fuxing Street
Guishan District
Taoyuan City
Taiwan
33305
+886 (0)975366192
yjding@cgmh.org.tw

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Do low skeletal muscle bulk and disturbed body fat mass impact tumor recurrence in stage I/II hepatocellular carcinoma undergoing surgery?

Study objectives
Body composition may influence stage I and II hepatocellular carcinoma (HCC) undergoing curative surgery.

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 20/01/2021, Institutional review board of Chang Gung Memorial Hospital (No. 199, Dunhua North Road, Taipei, 105, Taiwan; +886 (03)3196200#3709; yjding@cgmh.org.tw), ref: 201901879B0

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Other

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

Interventions
For preoperative tumor staging, all patients recruited will undergo computed tomography (CT) scans no more than 1 month before liver resection. Parameters of body composition will be acquired from non-contrast CT scans with a 5 mm slice thickness. Indices of body composition will be obtained and correlated with tumor recurrence.

Intervention Type
Other

Primary outcome measure
Disease-free survival is calculated from the date of surgery to the date of the first documented clinical disease recurrence and is estimated by Kaplan-Meier survival analysis

Secondary outcome measures
1. Early tumor recurrence, defined as recurrence of the tumor within 2 years of surgery
2. Overall tumor recurrence, defined as the occurrence of the tumor after surgery, measured in years

Overall study start date
01/02/2021

Completion date
31/07/2023

Eligibility

Key inclusion criteria
1. Stage I and II HCC patients who received curative liver resection at Linkou Chang Gung Memorial Hospital (CGMH)
2. Patients without cancer who received abdominal CT at Linkou Chang Gung Memorial Hospital (CGMH)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
90 Years

Sex
Both

Target number of participants
600

Total final enrolment
541

Key exclusion criteria
1. Patients who lacked critical clinical data or image
2. Received concomitant extra-hepatic surgery except for cholecystectomy
3. Underwent intra-operative vascular/biliary reconstruction
4. History of major operations or trauma within 3 months of liver surgery

Date of first enrolment
01/02/2012

Date of final enrolment
11/01/2021

Locations

Countries of recruitment
Taiwan

Study participating centre

Linkou Chang Gung Memorial Hospital
No, 5, Fu Hsing St
Taoyuan
Taiwan
33305

Sponsor information

Organisation
Linkou Chang Gung Memorial Hospital

Sponsor details
No. 5, Fuxing Street
Guishan District
Taoyuan City
Taiwan
33305
+886 (0)3281200-3366
alanlee@cgmh.org.tw

Sponsor type
Hospital/treatment centre

Website
http://www1.cgmh.org.tw/branch/lnk/e/index.aspx

ROR
https://ror.org/02dnn6q67

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Chang Gung Memorial Hospital, Linkou

Alternative Name(s)
Linkou Chang Gung Memorial Hospital

Funding Body Type
Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location
Taiwan

Results and Publications

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

Intention to publish date
30/06/2024

Individual participant data (IPD) sharing plan
The datasets generated or analyzed during the current study may be available upon request from Chao-Wei Lee (alanchaoweilee@hotmail.com), with the permission of the institution.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/11/2024	09/06/2025	Yes	No