

# The influence of body composition on liver cancer patients undergoing surgery

<b>Submission date</b> 30/04/2024	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 01/05/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 09/06/2025	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## 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

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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

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

**Study type(s)**

Other

**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(s)**

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

**Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Upper age limit**

90 years

**Sex**

All

**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

**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

## 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?
<a href="#">Results article</a>		01/11/2024	09/06/2025	Yes	No