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Integrating Chinese herbal medicine in advanced lung cancer: a multicenter real-world study using target trial emulation

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

Plain English summary of protocol

Background and study aims

Lung cancer is the leading cause of cancer-related deaths globally, with about 2.4 million new cases and 1.8 million deaths reported in 2022. Over 75% of cases are diagnosed at advanced stages, with a 5-year survival rate of only 5.2%. Non-small cell lung cancer (NSCLC) accounts for more than 80% of lung cancers. While targeted therapies, particularly EGFR-TKIs, extend progression-free survival, they are often limited by resistance and adverse effects. Chinese herbal medicine (CHM), commonly used in Asia, has shown potential in improving outcomes and reducing treatment-related side effects in NSCLC. This study aims to evaluate the feasibility and long-term impact of integrating CHM - specifically oral CHM - into advanced NSCLC management using real-world data and network pharmacology.

Who can participate?

Patients aged 18 to 80 years diagnosed with stage IV non-small cell lung cancer who have received oral Chinese herbal medicine as part of their treatment.

What does the study involve?

This is a retrospective analysis of clinical outcomes using real-world databases. The study will also use network pharmacology to analyze core CHM prescriptions and their potential molecular mechanisms.

What are the possible benefits and risks of participating?

As this is a retrospective study, there is no direct involvement or risk to patients. The findings may benefit future patients by optimizing integrative treatment strategies.

Where is the study run from?

Chang Gung Memorial Hospital, Taiwan

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

November 2023to February 2024

Who is funding the study?
The study is funded by the Chang Gung Medical Foundation, the Ministry of Health and Welfare and the National Science and Technology Council in Taiwan.

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
MOHW114-CMAP-M-113-000005-C

Study information

Scientific Title
The clinical outcomes of integrating Chinese herbal medicine in stage IV non-small cell lung cancer treatment: a multicenter real-world study using target trial emulation and system biology approach

Study objectives
Integrating Chinese herbal medicine (CHM) in the management of patients with advanced non-small cell lung cancer (NSCLC) may have a better long-term outcome than standard therapy alone.

Ethics approval required
Ethics approval required

Ethics approval(s)

approved 23/11/2023, The Institutional Review Board of the Chang Gung Medical Foundation (199, Tung Hwa North Road, Taipei, 10507, Taiwan; +886 (0)3 3196200; jocelyn320@cgmh.org.tw), ref: 202300142B0C502

Study design
Multi-center retrospective target trial emulation

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Stage IV non-small cell lung cancer.

Interventions
Chinese herbal medicine, modified according to illness and physicians' clinical experience (at least 28 days of oral Chinese herbal medicine treatment, twice to three times a day). The follow-up duration was set as 10 years after diagnosis or to the date of 31/12/2021.

Intervention Type
Supplement

Primary outcome(s)
Overall survival (OS), retrieved from the clinical database built up by the Chang Gung Medical Foundation, measured at the end of the study (31/12/2021) or 10 years after diagnosis

Key secondary outcome(s))
Cancer-specific survival (CSS), retrieved from the clinical database built up by the Chang Gung Medical Foundation, measured at the end of the study (31/12/2021) or 10 years after diagnosis

Completion date
13/02/2024

Eligibility

Key inclusion criteria
1. Patients newly diagnosed with stage IV NSCLC
2. Aged 18 to 80 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
80 years

Sex
All

Total final enrolment
6359

Key exclusion criteria
1. Patients aged <18 or ≥80 years
2. Errors in diagnosis or death date
3. Missing TNM staging records
4. Non-stage IV NSCLC, or cancer types other than squamous cell (SqCC) and adenocarcinoma (AC)

Date of first enrolment
01/01/2011

Date of final enrolment
31/12/2021

Locations

Countries of recruitment
Taiwan

Study participating centre
Chang Gung Memorial Hospital, Taiwan
No.5, Fuxing St., Guishan Dist.
Taoyuan City
Taiwan
333

Sponsor information

Organisation
Chang Gung Medical Foundation

Funder(s)

Funder type
Charity

Funder Name
Chang Gung Medical Foundation

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Taiwan

Funder Name
The Ministry of Health and Welfare, Taiwan

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Taiwan

Funder Name
National Science and Technology Council

Alternative Name(s)
National Science and Technology Council (Taiwan), National Science and Technology Council, R.O.C, National Science and Technology Council of Taiwan, Ministry of Science and Technology, Taiwan, Taiwan's National Science and Technology Council, , NSTC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Taiwan

Results and Publications

Individual participant data (IPD) sharing plan
The dataset analyzed in this study would be available upon proper request and approval from the Institutional Review Board of the Chang Gung Medical Foundation

IPD sharing plan summary
Available on request