

# A multi-centre study comparing idiopathic pulmonary fibrosis and combined pulmonary fibrosis and emphysema

<b>Submission date</b> 18/07/2023	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 13/08/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 05/09/2023	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Combined pulmonary fibrosis and emphysema (CPFE) and idiopathic pulmonary fibrosis (IPF) are progressive lung diseases with limited treatment options. This study aimed to compare the treatment outcomes of patients with CPFE and those with IPF receiving anti-fibrotic agents.

### Who can participate?

Patients with interstitial lung disease (ILD) with IPF or CPFE.

### What does the study involve:

The study involved following IPF and CPFE patients for a duration of 3 years and recording their survival outcomes.

### What are the possible benefits and risks of participating?

This study will investigate the prognosis of two lung diseases and identify possible underlying risk factors in both. There were no risks of participation as it was not an interventional study.

### Where is the study run from?

Taichung Veterans General Hospital (Taiwan)

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

June 2015 to November 2022

### Who is funding the study?

Taichung Veterans General Hospital (Taiwan)

### Who is the main contact?

Dr Pin-Kuei Fu, [paper199350@gmail.com](mailto:paper199350@gmail.com)

## Contact information

**Type(s)**

Principal investigator

**Contact name**

Dr Pin-Kuei Fu

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**Contact details**

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**Additional identifiers****Clinical Trials Information System (CTIS)**

Nil known

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

CE22228B

**Study information****Scientific Title**

Idiopathic pulmonary fibrosis with or without emphysema: a 3-year multi-centre study

**Acronym**

multiTaiCPFE2022

**Study objectives**

Patients with combined pulmonary fibrosis and emphysema (CPFE) treated with anti-fibrotic agents had survival outcomes similar to those of patients with idiopathic pulmonary fibrosis (IPF).

**Ethics approval required**

Ethics approval required

**Ethics approval(s)**

1. approved 12/05/2022, The Institutional Review Board of Taichung Veterans General Hospital (1650 Taiwan Boulevard Sect. 4, Taichung City, 407219, Taiwan; +886 (0)4 2359 2525; [imsc@vghtc.gov.tw](mailto:imsc@vghtc.gov.tw)), ref: CE22228B

2. approved 13/07/2022, The Institutional Review Board of National Taiwan University, Yun-Lin Branch (No.579, Sec. 2, Yunlin Rd., Taichung City, 640, Taiwan; +886 (0)5 6330002 #8521; Y03511@ms1.ylh.gov.tw), ref: 202206026RINA

3. approved 30/04/2022, The Institutional Review Board of China Medical University Hospital (No. 2, Yude Rd., North Dist., Taichung City, 404327, Taiwan; +886 (0)4 2205 2121; imc@mail.cmuh.org.tw), ref: CMUH111-REC2-077

4. approved 22/06/2022, The Institutional Review Board of Chang Gung Medical Foundation (No. 5, Fuxing St., Guishan Dist., Taoyuan City, 333, Taiwan; +886 (0)3 328 1200; syu2323@cgmh.org.tw), ref: 202200850B0

5. approved 23/08/2022, The Institutional Review Board of Chang Gung Medical Foundation (No. 5, Fuxing St., Guishan Dist., Taoyuan City, 333, Taiwan; +886 (0)3 328 1200; syu2323@cgmh.org.tw), ref: 202201260B0

6. approved 04/07/2022, The Institutional Review Board of E-DA hospital (No.1, Yida Road, Jiaosu Village, Yanchao District, Kaohsiung City, 82445, Taiwan; +886 (0)7 615 0011 #5765; ed111235@edah.org.tw), ref: EMRP-111-079

7. approved 05/08/2022, The Institutional Review Board of Ministry of Health and Welfare Taoyuan General Hospital (No. 1492, Zhongshan Rd, Taoyuan District, Taoyuan City, 330, Taiwan; +886 (0)3 3699721#3907; IHC@mail.tygh.gov.tw), ref: TYGH111040

8. approved 18/12/2018, Institutional Review Board of Taichung Veterans General Hospital (1650 Taiwan Boulevard Sect. 4, Taichung City, 407219, Taiwan; +886 (0)4 2359 2525; imsc@vghtc.gov.tw), ref: CE18325B

### **Study design**

Retrospective observational cohort study

### **Primary study design**

Observational

### **Study type(s)**

Other

### **Health condition(s) or problem(s) studied**

Patients with interstitial pulmonary fibrosis only (IPF) and patients with combined pulmonary fibrosis and emphysema (CPFE)

### **Interventions**

The study involved following IPF and CPFE patients for a duration of 3 years and recording their survival outcomes.

### **Intervention Type**

Other

### **Primary outcome(s)**

3-year survival rate measured using patients' medical records

### **Key secondary outcome(s)**

1. Pulmonary function measured using spirometer at baseline and every year for 3 years
2. Disease progression measured using Gender-Age-Physiology (GAP) score at baseline and every year for 3 years

### **Completion date**

28/11/2022

## **Eligibility**

### **Key inclusion criteria**

1. Patients with a definitive diagnosis of interstitial lung disease by a pulmonologist and confirmed by high-resolution computed tomography (HRCT)
2. Passed the health insurance review to pay for the anti-pulmonary fibrosis medications

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

All

### **Total final enrolment**

275

### **Key exclusion criteria**

1. Patients not fulfilling the criteria of interstitial lung disease
2. Patients not having health insurance to cover anti-fibrotic medications

### **Date of first enrolment**

01/08/2018

### **Date of final enrolment**

31/08/2022

## **Locations**

### **Countries of recruitment**

Taiwan

### **Study participating centre**

**Taichung Veterans General Hospital**  
1650 Taiwan Boulevard Sect. 4

Taichung City  
Taiwan  
407219

**Study participating centre**  
**National Taiwan University, Yun-Lin Branch**  
No.579, Sec. 2, Yunlin Rd.  
Douliu City  
Taiwan  
640

**Study participating centre**  
**China Medical University Hospital**  
No. 2, Yude Rd., North Dist.  
Taichung City  
Taiwan  
404327

**Study participating centre**  
**Chang Gung Medical Foundation**  
No.5, Fuxing St., Guishan Dist.  
Taoyuan City  
Taiwan  
333

**Study participating centre**  
**E-DA hospital**  
No.1, Yida Road, Jiaosu Village, Yanchao Dist.  
Kaohsiung City  
Taiwan  
82445

**Study participating centre**  
**Ministry of Health and Welfare, Taoyuan General Hospital**  
No. 1492, Zhongshan Rd, Taoyuan Dist.  
Taoyuan City  
Taiwan  
330

# Sponsor information

## Organisation

Taichung Veterans General Hospital

## ROR

<https://ror.org/00e87hq62>

# Funder(s)

## Funder type

Hospital/treatment centre

## Funder Name

Taichung Veterans General Hospital

## Alternative Name(s)

, TCVGH

## Funding Body Type

Government organisation

## Funding Body Subtype

Local government

## Location

China

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analyzed during the current study will be available upon request from Dr Pin-Kuei Fu ([yetquen@gmail.com](mailto:yetquen@gmail.com))

## IPD sharing plan summary

Available on request