

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

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| Submission date 18/07/2023 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 13/08/2023 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 05/09/2023 | Condition category 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

Contact information

Type(s)

Principal Investigator

Contact name

Dr Pin-Kuei Fu

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Contact details

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

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), 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

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

Not applicable

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 measure

3-year survival rate measured using patients' medical records

Secondary outcome measures

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

Overall study start date

01/06/2015

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

Age group

Adult

Sex

Both

Target number of participants

>250

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

Sponsor details
1650 Taiwan Boulevard Sect. 4
Taichung
Taiwan
407219
+886 (0)4 2359 2525
janniferlee@gmail.com

Sponsor type
Hospital/treatment centre

Website
<http://www.vghtc.gov.tw/GipOpenWeb/wSite/mp?mp=8>

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

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

31/12/2023

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)

IPD sharing plan summary

Available on request