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

Submission date
18/07/2023

Recruitment status
No longer recruiting

Registration date
13/08/2023

Overall study status
Completed

Last Edited
05/09/2023

Condition category
Respiratory

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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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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