

EFFECT OF PIRFENIDONE IN PATIENTS WHO DEVELOPED PULMONARY FIBROSIS AFTER RECOVERING FROM EXPOSURE TO COVID-19.

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ABSTRACT

In this research paper, the researcher referred to the collection of random samples of varying ages recovering from Covid-19 to determine the symptoms that appear on them immediately after recovery, and it was noticeable on the majority of those who recovered from Covid-19 the occurrence of health problems associated with Covid-19, which was clarified and concluded. Through those who recovered, the syndrome was prevalent in all patients with Covid-19 after recovery, pulmonary fibrosis syndrome, where all the acute and serious symptoms indicated acute shortness of breath. And because pulmonary fibrosis syndrome and its acute symptoms cause death, medical efforts were combined to develop drugs for respiratory crises and to analyze healthy ratios and concentrations to determine the effective drugs that can be adopted as a course of treatment to get rid of pulmonary fibrosis syndrome associated with Covid-19, and one of the most important drugs referred to is Pirfenidone, which is known. The brand name Perfinex is what was used on randomized samples that were selected to evaluate its effectiveness and the length of time that the drug can treat this syndrome.

Keywords: Covid-19, Pirfenidone, Pulmonary, fibrosis, infection

INTRODUCTION

The emergence of Covid-19 was not the real crisis that the health staff faced to not find a suitable drug for it, but the actual crisis in which the doctors fell was to find actual solutions to the crises and problems caused by the virus, and the prevailing syndrome that the recovering from Covid-19 was exposed to was pulmonary fibrosis, We can give an actual overview of pulmonary fibrosis and its symptoms, and pulmonary fibrosis consists of two types, namely (FDA, 2021)

- Severe acute respiratory syndrome (SARS)
- Middle East Respiratory Syndrome (MERS)

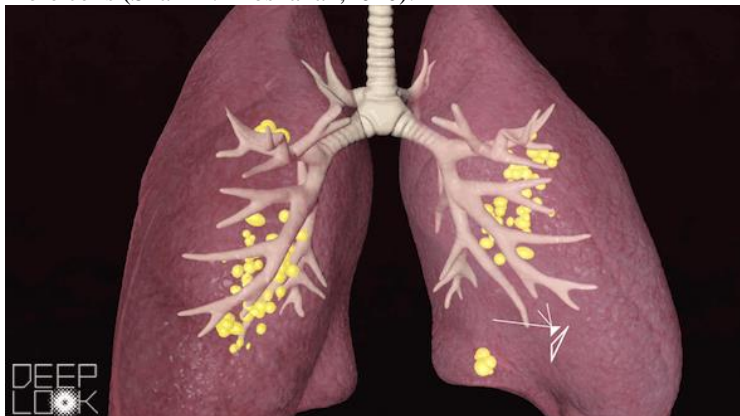
And acute shortness of breath syndrome (ARDS) occurs. When fluid builds up in the small, flexible air sacs (alveoli) in lungs. The fluid keeps lungs from filling with enough air, which means less oxygen gets into bloodstream. This deprives organs of the oxygen they need to function. Serra López-Matencio et al (2021)

Acute shortness of breath syndrome usually occurs in people who have severe illness or trauma. Severe shortness of breath - the main symptom of ARDS - usually occurs between a few hours and a few days after an injury or infection. Seifirad S. (2020)

Most people with ARDS don't live long. The risk of death increases with age and disease severity. Among people who survive ARDS, some make a full recovery while others experience permanent lung damage.

How does Covid-19 invade the lung?

Corona virus penetrates into the body when the respiratory system inhales it, when a close person coughs or touches a contaminated surface and then touches the face after that. During the incubation period, the virus establishes its presence in the body, enters the cells that make up the body, and then seizes them. George, P. M., Wells (2020). The incubation period, which is the period between infection with the virus and the appearance of symptoms, varies greatly from person to person, but on average it is days and may reach 14 days. The virus first infects the cells lining the throat, trachea and lung, so that they make huge quantities of other viruses that infect more cells (Shari B. Brosnahan,2020).



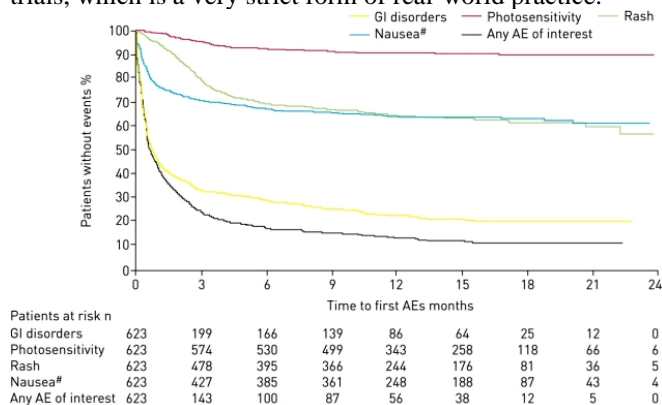
The yellow clusters represent lung damage inflicted by the disease COVID-19. (Teodros Hailye/KQED)

MATERIALS AND METHODS

A sample was randomly selected from those recovering from Covid-19, and the percentage of those recovering was estimated to be 72 recoveries, and their pulmonary fibrosis was observed, and they were given perfenidone during the data recording period, to evaluate the cases and determine the emerging data, to determine the increase in the sample size or the lengthening of the treatment period to provide the appropriate strength to evaluate the report. In addition to reaching outcome measures for primary and secondary efficacy, the changes increased the strength of the study as it showed statistically significant effects on the primary and secondary endpoint analyzes. The primary endpoint of efficacy remained a change in forced vital capacity (FVC) and delivery of approximately 97% of the increased sample volume for the duration of treatment with detection of 50% of forced vital capacity. Patients were randomly assigned at a ratio of 2: 2: 1 to receive pirfenidone 2403 mg / day, or pirfenidone dail

RESULTS

The trial was based on three clinical trials of patients with pulmonary fibrosis syndrome, and the third phase of pirfenidone was for those with forced vomiting capacity (FVC), which reached 50% of the predicted and diffuse capacity of carbon monoxide (DLCO) by 35%. The percentage reported pre-FVC of 50-90% before and DLCO at 30% before (ascending). The results confirmed the marked decrease in kidney function, in addition to the decline of the disease or its slow movement, which helped reduce the mortality rate in patients who were treated with pirfenidone. Continuity in treatment confirmed the progression of the disease through analyzes combined with clinical trials, which is confirmed by the results is the continuity of treatment. Through clinical trials, we notice differences in the characteristics of data analysis besides the baseline, which provides long-term follow-up of data, as interpretations and analyzes of real data benefit by reference to the criteria included through clinical trials, which is a very strict form of real-world practice.



The picture shows the randomized analysis based on associated adverse events (AE) for the first time that it was measured through random distribution, and regardless of the actual duration of treatment, the clinical trials that were collected in three stages were related to the digestive system, which caused nausea, and digestive disorders.

Table 1 Other baseline characteristics (all randomized patients)

baseline characteristics	Perfenidone 1197mg/d (N=87)	Perfenidone 2403 mg/d (N=174)
FVC %		
Mean = SD	87	174
Median	75	74 = 14
Range	52	73
Supplemental oxygen use.		
Yes	15	29
No	71	145
IPF diagnosis by HRCT		
Definite IPF	83	159
Probable IPF	4	14
Uncertain IPF	0	1

Table 2: Change from baseline in FVC (% predicted) – PIPF-004

	1197mg/day	2403 mg/day	Placebo
12 weak			
SD	-1.2	1.2	-2.7
Median	-0.7	-.06	-1.3
P-value		P=0.0610	
48 weak			
SD		-4.4	-9.2
Median	-6.4	-3.0	-4.6
P-value	-2.6	p-0.0009	
Weak 60			
SD	-8.6		
Median	-4.4	-6.6	-10.7
P-value		-3.7	-5.9
		P=0.002	

DISCUSSION

The sample that includes patients was defined with (ITT), and the first effective point is the absolute change from the baseline which is week 72%, and FVC was evaluated before randomization for every 12 weeks until the end of the study, data for patients who died (calculated as a predicted percentage FVC = 0%) was classified according to time to death, with the shortest time to receive the worst rank; change in forced vital capacity between examination and first day 10% We note in these results the changes that occur over time, so the difference between 2403 mg / day was clear from week 12, where the significance was achieved from week 24, where the difference between the active quarter strips with high groups was approximately 25%, and the efficacy of pirfenidone was apparent in terms of percentage. The expected percentage of forced vital capacity, and provides evidence that 2403 mg / day does better than 1197 mg / day in active patient interaction. (Fernandez Perez AR, Daniels C, Schroeder DR 2010, p. 137)

CONCLUSION

The study tried to find a solution to eliminate the pulmonary fibrosis syndrome associated with Covid-19 virus, and the most prominent conclusions reached by the study were the following:

-The drug pirfenidone gave positive results in the treatment of lung function, and with the continuation of it the results were better. One of the negative symptoms that appeared through the drug is a feeling of nausea.

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request

Conflicting Interest (If present, give more details): No Conflict of Interest

No financial disclosure

-Acknowledgements

Not applicable

Declarations

-Ethics approval and consent to participate

Written informed consent was obtained from all patients and the study was approved by the research ethical committee of Faculty of Pharmacy, Omar Al Mukhtar University (International review board IRB #:6372-1-3-2020). The study was done according to The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

-Consent for publication

Not applicable

Competing interests

The authors declare that they have no competing interests.

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