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# 3-DAY COURSE OF LOW-DOSE SUBCUTANEOUS ANAKINRA IN PATIENTS WITH REFRACTORY MODERATE-SEVERE COVID-19: A PROOF-OF-CONCEPT STUDY.

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## Background and importance

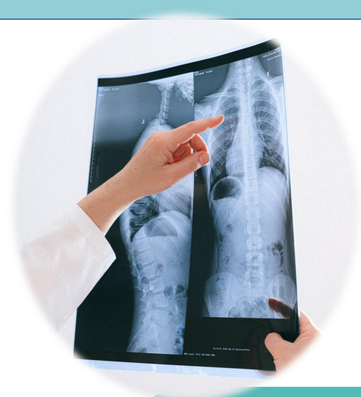
Many patients with moderate-severe COVID-19 develop a disregulated immune response, elevation of acute phase reactants and the release of **proinflammatory cytokines** such as and IL-6, thus leading to a **state of hyperinflammation.**

## Objectives and aims

To determine whether a **3-day course of low-dose subcutaneous anakinra (LDSA)** provides a benefit in refractory moderate-severe COVID-19.

## Materials and methods

**2 hospitals**
**April 1-May 8, 2020**



### Prospective study

- Hospitalized patients refractory to standard-of-care treatment
- PCR+ SARS-CoV-2 radiological pneumonia
- >5 Days symptoms
- Moderate-severe COVID-19 according to clinical/analytical criteria.

### Anakinra

**100 mg** daily sc x 3 consecutive days

### Primary outcome

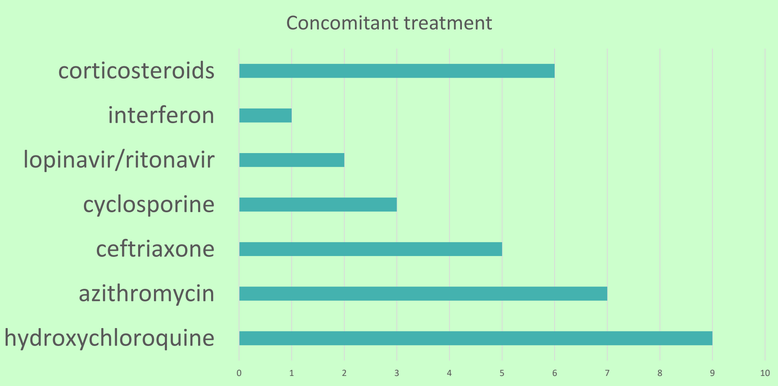
- **Radiological** and **clinical** improvement 72 hours after the first administration

### Secondary outcome

Incidence of serious adverse events, mortality, need for invasive ventilation at D3 and D14, and days of hospitalization

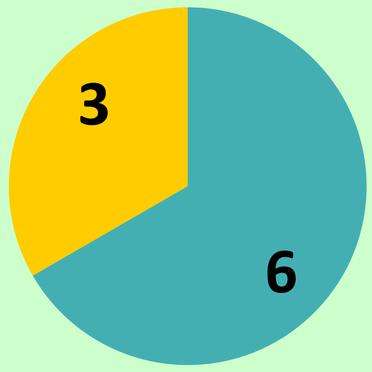
## Results

9 patients (age 48-88; 5/9 female) with bilateral pneumonia Median oxygen saturation (SpO2) at D0 was 92% with a significant improvement of 97% (p=0.007) at D3.
Anakinra was introduced between 1 and 17 days (median 8 days) after admission.




**Primary outcome**

Radiological and clinical improvement 72 hours after 1st Anakinra 100mg sc dose




- Significant differences were also observed in several of the laboratory parameters analysed between baseline and D3 (Figure 1)
- No serious adverse events were observed. None patients required admission to the intensive care unit or invasive mechanical ventilation in D3 and D14. One patient died after 21 days of hospitalization, the remaining 8 were discharged (length of stay 6-45 days).

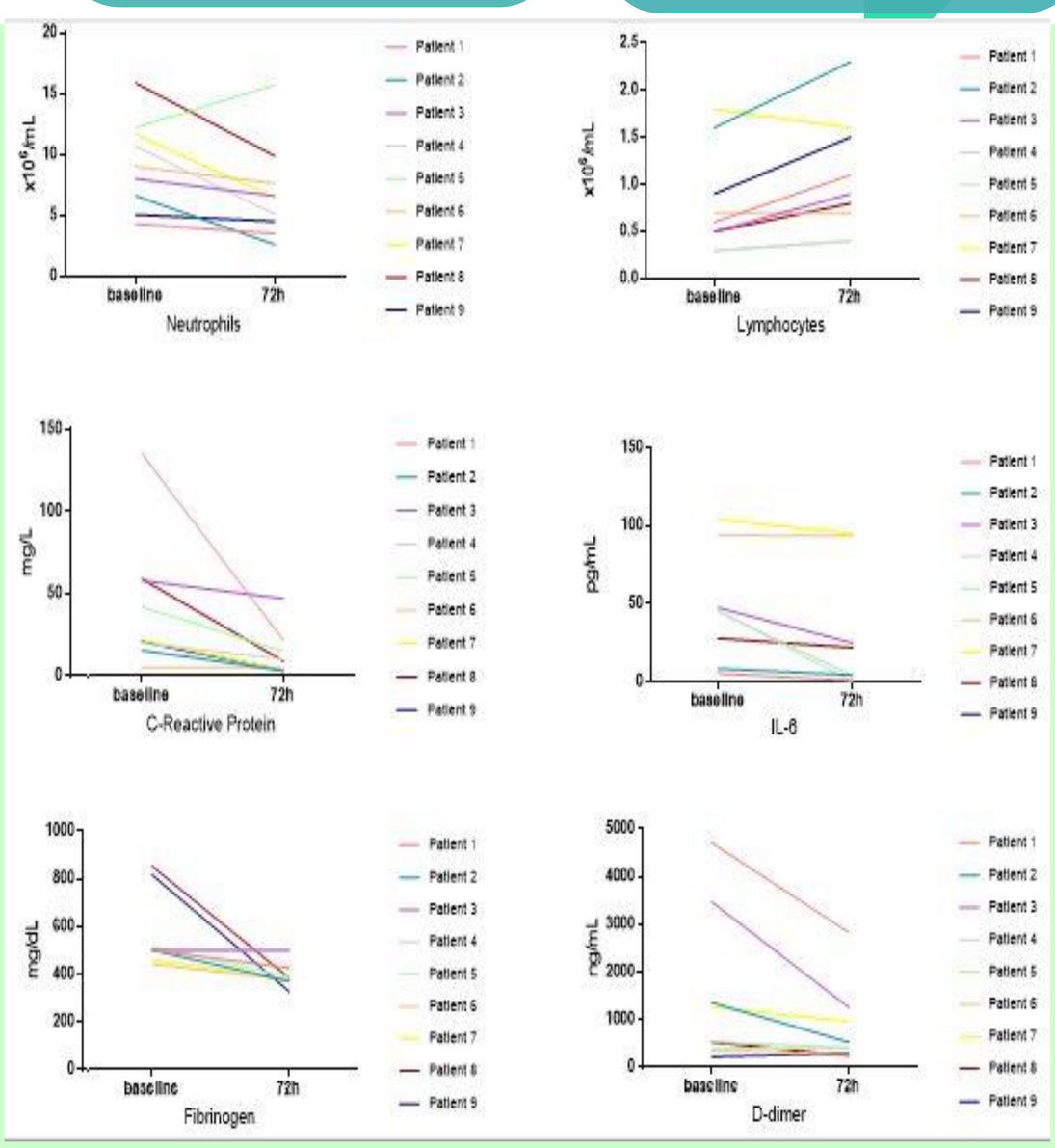



Figure 1: Changes in laboratory parameters over time in patients with refractory moderate–severe COVID-19 who received a 3-day course of LDSA

## Conclusion and relevance

In this study of patients with refractory moderate-severe COVID-19,a 3-day course of low-dose subcutaneous anakinra was **effective and safe**, resulting in radiological, clinical, and analytical improvement in most cases.
These observations require further evaluation in clinical trials.