

Mycotherapy trial in one of the groups most vulnerable to infection: nursing home residents

STUDY IN NURSING HOME RESIDENTS DEMONSTRATES A REDUCTION IN BOTH MORTALITY FROM AND ASSOCIATED COMPLICATIONS OF COVID-19

- Preliminary results of the benefits of supplementation with immunomodulatory nutraceuticals by Hifas da Terra in nursing home residents diagnosed with COVID-19
- Preliminary results show that the expected fatality rate in this at risk group of patients was reduced from 24.1% to 1.4%
- More than 88% of the patients who followed the prescribed protocol did not manifest complications associated with COVID-19 and none required admission to the ICU (hospital admission dropped from 27% to 12.3%)
- These results demonstrate that supplementation with nutraceuticals of mushroom origin developed by Hifas da Terra could be useful in the coadjuvant treatment of patients with COVID-19, especially in the groups most vulnerable to infection

Pontevedra, 20th October 2020. Hifas da Terra's (HdT) biotechnology laboratory released the preliminary results of the trial of mycotherapeutic supplements in nursing home residents diagnosed with COVID-19, which demonstrated that supplementation with immunomodulatory nutraceuticals can significantly improve the situation of those most vulnerable to the pandemic by reducing both mortality and complications associated with infection by SARS-COV-2.

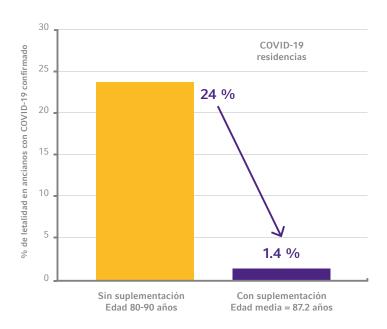
The study carried out between April and May 2020, in one of the population groups most vulnerable to the virus, details the **favourable results** and improved health status of 73 residents of a nursing home in Madrid diagnosed with COVID-19 (via CRP and / or serology) who undertook the supplementation protocol. Nursing home residents represent a **high-risk group** since they are elderly, have weak immune systems, and on average have at least three active previously diagnosed conditions.

Decrease in mortality

After supplementation with immunomodulatory nutraceuticals, the group of patients with an average age of 87.2 years had **reduced mortality associated with COVID-19**. The expected **fatality rate was reduced from 24% to 1.4%**, the first value represents the official mortality data from the Spanish **Ministry of Health** for the 80-90 year old age group, on April 21, 2020, when the study was conducted.

The decrease in mortality rates is also significant when compared with the **expected mortality** rate in similar age groups, estimated at **42% by the Ministry of Health**.

Reduction of the expected fatality rate in high-risk patients diagnosed with COVID-19 in nursing homes after the supplementation protocol with immunomodulatory nutraceuticals.



Source: Observational study of 73 elderly patients with COVID-19 supplemented with Immunomodulatory nutraceuticals from Hifas da Terra at the Geriatric Medical Assistance Center of Leganés (Madrid)

Associated complications

The results of the study also show that the patients who were administered the supplementation **did not present with associated complications**, and that there was a **reduction in the expected hospital admission rates from 27% to 12.3%** compared to national averages. If we take data from international studies as a reference, the average hospital admission rate goes up to 54%.

Intensive Care Unit (ICU) admissions

Despite the severity of the infection in the study group, the patients who received supplementation and were admitted to hospital **did not get worse**. The positive disease progression **avoided the need for admission to the ICU** in all cases, compared to the expected rate of admissions for this age group, which would be 3.7%, according to the data provided by the Spanish Government.

Dr. **Manuel Soler**, the doctor and scientist in charge of the study entitled, "Mycotherapy Could Reduce Mortality and Complications Associated with COVID-19 in the Elderly in Spanish nursing homes" points out that, "the preliminary trial data has great clinical significance for the treatment of COVID-19 as it was carried out in patients exposed to greater risk of transmission of the virus."

"The impact is even greater if the high **mortality rate due to COVID-19** in the elderly is taken into account, which in nursing homes has reached **close to 70**%, as recently published," says **Dr. Soler**.

As explained by the R&D director of Hifas da Terra, **Dr. Esteban Sinde**, the protocol designed for this trial "provides mycotherapeutic compounds with immunomodulatory and anti-inflammatory activity that have proven to be useful in the prevention and coadjuvant treatment of multiple viruses."

"We are currently working on an action hypothesis focused on the immunomodulatory action of our nutraceuticals to regulate hyperinflammation and the cytokine storm that occurs as a result of infection by this coronavirus," he adds.

Although this is preliminary data, conclusions can be made about the potential for the prevention and slowing down of the progression of SARS-COV-2 infection, which "could open up an avenue of coadjuvant support to conventional medical treatments, especially for other affected nursing homes." This could mean an increase in trial participants and locations in the coming months including new organisations and health professionals from all over the world.

About Hifas da Terra

Hifas da Terra is a biotechnology company born out of research and innovation, which specialises in the development of mycotherapeutic healthcare products (those made using bioactive molecules of fungal origin).

Among other scientific milestones, this biotech company has managed to identify fungal strains with anticancer potential (the FungiTechOnco project) and to determine the anti-migration effect of fungal compounds on tumour cells. These results were presented at the 16th International Congress of the Spanish Association for Cancer Research (ASEICA).

Hifas da Terra's strong values of research, innovation and sustainable development have made their laboratory an example recognised by the Xunta de Galicia, and the Spanish Government, and HdT have been awarded more than 13 distinctions in business excellence.

Hifas da Terra has one of the largest banks of fungal strains of medicinal interest in Europe. Currently, HdT's private "fungi bank" is larger than the Spanish Collection of Culture Types (SCTC).

Hifas da Terra has a pioneering research center for the development of new cultivation techniques, optimising bioavailability and standardising production processes to maintain a high concentration of bioactive fungal compounds (with several patents under development).

Hifas da Terra's products are available in Germany, the United Kingdom, Ireland, Portugal, Italy, France, and others via subsidiaries or distribution agreements. These products represent a benchmark in the development of GMP certified food supplements in the European market. The company has a promising and ambitious expansion plan for 2021 including the recent openings in the American, Asian, and Middle Eastern markets.

About the trial protocol

- · A specific protocol of immunomodulating mycotherapy nutraceuticals was trialed with 73 resident patients of the Geriatric Medical Assistance Center of Leganés with an average age of 87.2 years.
- · The participants received supplementation and monitoring for 40 days between April and May 2020.
- · The diagnosis for COVID-19 was made by PCR and / or serology.
- Due to the fundamental objective of enhancing the health of this group vulnerable to the SARS-CoV-2 coronavirus in a period of deep health crisis, it was decided to limit the inclusion of a control group so that no patient was denied mycotherapeutic supplementation.

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