HIFAS da TERRA®

MUSHROOM BIOSCIENCE

CLINICAL TRIAL

Hifas da Terra and the Fundación Médica Galicia Sur start a new clinical trial of a natural immunomodulator for colorectal cancer

- **The trial includes a formula developed by Hifas da Terra using natural bioactive compounds from specific medicinal mushrooms**
- **The formula will be evaluated in relation to the rate of postoperative complications, as well as the modification of gut microbiota, the reduction of inflammatory parameters and overall digestive wellbeing, all aspects related to the trial participants' immune response**
- **A total of 144 patients will participate in this randomised double-blind clinical trial to be launched at the University Hospital of Ourense in the coming months**
- **Participation will be offered to patients with colorectal cancer who are candidates for surgery with curative intent**
- **This study is part of the final phase of the collaborative R&D Micromarker project, co-led by the biotech company Hifas da Terra and supported by the CDTI, the Spanish government's funding mediator for business R&D**

Pontevedra, 15 May 2021.- The Pontevedra-Vigo-Ourense Research Ethics Committee has just authorised a **clinical trial, NCT04821258,** promoted by the **Fundación Biomédica Galicia Sur** in which, **for the first time, a nutraceutical made by Hifas da Terra** from specific medicinal mushroom extracts will be included with the aim of **reducing the risk of postoperative complications**.

This **randomised double-blind clinical trial will evaluate the effect of the administration of the nutraceutical MICODIGEST 2.0 prior to surgery on complications associated with colorectal cancer surgery treated with curative intent**. It is a pioneering trial in the field of oncology which will **evaluate how the prebiotic and anti-inflammatory effects of the nutraceutical developed by Hifas da Terra can reduce postoperative complication**s that affect 20% of patients who undergo surgery.

Anti-inflammatory and Microbiota modulation effects

According to the R&D department of Hifas da Terra, inflammation and suboptimal gut microbiota are complications which are also risk factors for the recurrence of disease in various types of neoplasms. They add, **"we know that the bacteria present in the microbiota can play an important role in the prevention of colorectal cancer. In this study, we will look at the inflammatory effects of microbiota modification. The application of the nutraceutical MICODIGEST 2.0, due to its anti-inflammatory and microbiota modulating effects, will hopefully have a positive effect on patients' immune response"**.

Micromarker Clinical Trial

The R&D Micromarker project launched in 2018 in collaboration with Anfaco-Cecopesca, **is evaluating the relationship between gut microbiota modulation and colorectal cancer progression**. This evaluation began with *in vitro* and animal model studies and went through various phases prior to testing in patients. The results of these initial phases allowed for the formulation of a final product made from the extracts with the best prebiotic and anti-inflammatory activity demonstrated *in vitro*.

The conclusions from these initial study phases have led to the development of the formula which will be tested by the trial patients. The production process for this formula is now protected under patent, following a favourable report from the Spanish Patent and Trademark Office.

Medicinal mushrooms as modulators of the microbiota in cancer

Although certain genetic factors contribute to the development of colorectal cancer, the gut microbiota or gut flora appears to play an important role in its development and progression and in the quality of life of these patients. **Dysbiosis or imbalance of microorganisms present in the normal microbiota, and inflammation are common features in patients with colon and rectal cancer**, as well as being two of the most important mechanisms related to the cancer disease process.

The microbiota is the community of microorganisms that live in the human gut on a regular basis, maintaining a symbiotic relationship. Most are bacteria that maintain a delicate balance with other microorganisms and are beneficial to the body, as they are involved in numerous physiological processes such as the metabolism of certain carbohydrates, activation of the immune system, regulation of intestinal cell growth and the synthesis of certain vitamins, such as B and K vitamins.

A poor gut microbiota may contribute to the development of cancer and various metabolic disorders leading to inflammation in the gut, liver and brain. Studies show that taking medicinal mushrooms influences the microbiota, but controlled clinical trials in patients are needed to fully understand the multiple benefits of medicinal mushrooms in cancer and human health.

This clinical trial will provide analytical data on inflammatory markers and other clinical data related to digestive wellbeing, before and after ingestion of MICODIGEST 2.0. **"We have already studied the effect of mushrooms on the immune system, but this new study will allow us to assess their ability to modify the intestinal microbiota and how mushroom extracts act positively against certain markers such as inflammation,"** adds Catalina Fernández de Ana, founder and chairwoman of Hifas da Terra.

Hifas da Terra

Hifas da Terra is a **biotechnology company focused on research and innovation, specialised in the development of healthcare products** based on bioactive molecules of fungal origin.

Among other scientific milestones, Hifas da terra has managed to identify fungal strains with anti-cancer potential **(FungiTechOnco project)** and to determine their **anti-migratory effect on tumour cells**. The results of this study were presented at the **16th International Congress of the Spanish Association for Cancer Research (ASEICA)**.

Hifas da Terra's founding principles based on **research, innovation and sustainable development** have made this laboratory an example recognised by the Xunta de Galicia and the Spanish Government with more than 13 distinctions in business excellence.

Hifas da Terra's scientific team has one of the largest banks of fungal strains of medicinal interest in Europe. Its private fungal bank is currently larger than the **Spanish Type Culture Collection (CECT)** of fungal strains.

Hifas da Terra is also a **pioneering research centre in the development of new cultivation and optimisation techniques for homogeneous production of medicinal mushrooms with a high concentration** of bioactive substances of fungal origin (with several patents under development).

Hifas da Terra is present in **Germany, United Kingdom, Ireland, Portugal, Italy, France**, and more, through subsidiaries or distribution agreements, and is a reference in the development of certified food supplements throughout the European market. The company has a promising and ambitious expansion plan for 2021, including recent openings in the American, Asian and Middle Eastern markets.