



Fund “Nauka” Project № 22026 Resume – Competition-Based Session 2022:

“Effects of cancer rehabilitation and Cordyceps in breast cancer patients”

Project leader: Prof. Paraskeva Mancheva Draganova, MD, PhD, DSc

Breast cancer is one of the most common types of cancer in the world, which, considering the high medico-social significance of the problem, requires the development of innovative methods of prevention, treatment and rehabilitation. Therapy with cytotoxic drugs has been the foundation of systemic drug treatment of breast cancer for decades. Despite its positive effects, chemotherapy damages healthy cells, which determines the low tolerance and adverse drug reactions. The synergy between cytostatic therapy and Cordyceps has been researched and established both in terms of specific cytostatic selection and dosage of chemotherapeutic drugs. The preservation of the upper extremity's function requires the development and integration of innovative physiotherapeutic programmes for patients with breast cancer. The project proposal implements an innovative and original combination of methods, developed by the research team (clinical, chromatographic, functional, questionnaire and statistical) to influence the side effects of chemotherapy and to correct the lymphedema of the upper extremity.

The aim of the project is to study and assess the combined effect of oncorehabilitation and Cordyceps on quality of life improvement among patients with breast cancer, who have undergone chemotherapy. The acquired project results:

- A new analytical method for chromatographic analysis was developed with mass-selective detection of Paclitaxel (PTX) in EDTA-plasma. The method has been validated according to the ICH M10 guidelines for "Bioanalytical Method Validation" (USFDA 2022). Paclitaxel concentration in the analysed plasma samples at 2.5 hours after the end of the infusion ranged between 116 ng/ml and 1878 ng/ml with a mean value of 613.09 ± 588.1 ng/ml and no detection of the drug in the samples at 16.5 hours. The developed method presents a reliable, rapid and consistent alternative for qualitative determination of Paclitaxel in plasma after intravenous administration of the drug. The validated method, is selective, sensitive, linear in a wide range of concentrations (from 50 to 3000 ng/ml), with a one-step sample preparation, appropriate for PTX determination in blood plasma after intravenous administration of the drug.

- An oncorehabilitation programme implemented among female patients with breast cancer, who have undergone chemo- and radiotherapy, was developed based on the results from a study on rehabilitation methods in world practice. Scientific evidence on the effect and necessary dosage of Cordyceps among cancer patients was taken into consideration. The benefits of integrating Cordyceps in clinical practice are aimed at preventing

complications and relapses of oncological and chronic diseases and at its possible use as an adjuvant therapy. An assessment of quality of life was performed using the WHO-QOL-BREF questionnaire, as well as functional methods. The complex positive effects of the oncorehabilitation programme and Cordyceps on the somatic and psychological health, and social adaptation were established.

The contemporary view on oncorehabilitation is related to the holistic nature of human health, which requires efforts to be dedicated towards treatment of oncological diseases and prevention of complications, arising during the course of the disease. The expected results from the method integration were connected to reduced financial expenses of the health and social systems of the country.