Project 7.3 Colitis induced by treatment with checkpoint inhibitors: a prospective observational study

Supervisor: dr hab. n. med. Edyta Zagórowicz
Institute: Maria Skłodowska-Curie National Research Institute of Oncology
Unit: Department of Gastroenterology Oncology
www: https://www.pib-nio.pl/

Background:

Immunomodulatory drugs are currently widely used in the treatment of malignant tumors: melanoma, non-small cell lung cancer, kidney cancer, skin cancers, head and neck cancers. Along with improved survival and prognosis, the use of immunotherapy is associated with the risk of autoimmune side effects, which primarily affect the skin, gastrointestinal tract and endocrine system. Diarrhea is one of the most common symptoms affecting the digestive system. In addition to infection, checkpoint inhibitors induced colitis is firstly taken into account in the differentiation of its cause. It is a separate disease entity that has many features resembling ulcerative colitis and Crohn's disease. The incidence of immunotherapy-related enteritis and colitis is ~10% with anti-CTLA4, ~1% with patients undergoing anti-PD1, and ~15% with combination of anti-CTLA4 and anti-PD1. In the latest (2022) guidelines of the European Society for Medical Oncology (ESMO), endoscopic examination of the large intestine with sampling is recommended in patients with grade >1 diarrhoea. In patients with diarrhea of the 2-4th degree, immunotherapy is discontinued and systemic glucocorticoids are prescribed, and in the absence of improvement, infliximab or vedolizumab. The decision to reintroduce immunotherapy is made individually.

Aim:

We are planning a prospective cohort study to see if patients who develop grade 2 or 3 diarrhoea during immunotherapy, and who are treated by gastroenterologists specializing in inflammatory bowel disease and are treated according to ESMO guidelines, will benefit from this in terms of a longer mean duration of immunotherapy compared to patients with the same complication. who will remain under the care of oncologists themselves. The studied cohort (Cohort A) will be subsequent patients undergoing immunotherapy treated at the Soft Tissue and Bone Cancer Clinic in whom the oncologist finds diarrhoea in grade 1, 2 or 3 toxicity. The control group (Cohort B) will be patients with the same complication during immunotherapy, treated in other PIB NIO clinics.

Requirements:

- the doctoral student should be a medical doctor with a specialization or in the course of specialization in internal medicine or gastroenterology or oncology with the possibility of practice at the National Institute of Oncology,

Its tasks will include:

- providing care for patients referred for consultation to the Gastroenterology Oncology Clinic team due to diarrhoea in accordance with ESMO guidelines and the study protocol,
- documentation of the course of treatment of patients referred to the team,
- evaluation of treatment results according to the study protocol,
- comparison of treatment outcomes of Cohort A and Cohort B based on data from hospital records in the Clininet database,
- participation in data analysis and dissemination of results