

Unique dualism of new antineoplastic and antimetastatic medicine iLive (The report on phase 1 clinical trial at patients with colorectal cancer and metastatic defeat of a liver)

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Introduction: The unique dualism was found during the preclinical researches of iLive. iLive has the expressed antineoplastic and anti-metastatic effect and is the modifier of antineoplastic action. The medicine suppresses development of tumor processes, promotes regress of tumors by their resorption; has impact on metastatic process, reducing metastatic level at simultaneous slowing of increase of primary tumors.

The unique dualism shows as direct growth inhibition of tumors and activating of different parts of immune system, showing immunoregulatory properties.

At the stage of preclinical trials, iLive showed considerable direct antineoplastic action, the index of growth inhibition of tumoral cells made 48, 77% that corresponds to activity of classical chemotherapeutic medicines, however toxic effects were absent (toxicity class V). Under the influence of iLive, the cytotoxic activity of NK cells significantly rises; functional activity of Th1 on production of IFN- γ and TNF- α increases and activity of Th2 on production of IL-4 decreases.

Purposes: Main goals of the trial were:

1. Preliminary estimation of iLive efficiency (based on its double action) which was defined by the following methods:
 - changes of volume of metastasizes were evaluated in dynamics using instrumental methods of examination (CT, X-ray, ultrasonic examination of abdominal cavity organs), it was done for the determination of the fact of progression, regression or disease stabilization, regression and stabilization duration were also estimated
 - the general survival was estimated
 - immune and CEO indexes were estimated
2. Confirmation of iLive safety which was determined as follows:
 - The estimation of therapy toxicity on scale recommended by WHO and the International anticarcinogenic union was carried out.
 - The estimation of the subjective status of patient on Karnovsky scale was carried out.

Methods: In described clinical trial, 40 people took part. They had the IV stage of colorectal cancer (T1-4N0-2M1 on TNM system); palliative surgical treatment (removal of primary tumor) was executed; the unresectable liver metastasizes were diagnosed during the operation (I, II stages of metastatic defeat of liver on the unified classification and confirmed by auxiliary methods (CT, X-ray, ultrasonic examination). Patients were divided into four groups: control group and three treatment groups with different dosage regimen of Ayliv. To patients of all groups, the standard chemotherapy in the de Gramont regimen (5- fluorouracil, leucovorin) was administered. The course of chemotherapy lasted 2 days and repeated each 2 weeks, treatment continued within 6 months.

Results: Due to unique dualism of iLive the following results were received:

1. The adverse events revealed during the trial weren't connected with iLive, it can be considered nontoxic and safe medicine.
2. At 70% of patients of the treatment groups, the stabilization of the disease was observed and at 10%, the regression of the disease was observed (on the basis of volume and quantity estimation of metastasizes), in control group only 40% had stabilization of the disease, and there were no cases of disease regression in control group.
3. All patients of the treatment groups finished the research. While in control group, 20% of patients died.
4. Immune and REO indexes were better in the treatment groups

Conclusions: The iLive is safe and effective medicine, due to unique dualism, it is a perspective medicine for adjuvant and neoadjuvant therapy of various oncological diseases and all data confirm the necessity of starting of new phase 2 clinical trial.