

CONCLUSION

On results of the limited clinical trials of Amitozyn preparation on the patients with malignant neoplasms and studying the immunomodulatory properties of the preparation in the Institute of Oncology, Academy of Medical Sciences of Ukraine (approved by director of the institute 25.12.2001)

The experimental investigations made on the Luis' carcinoma model, showed that Amitozyn had no significant influence on the animals lifetime, the preparation also prevented from the new metastases formation, but not inhibited the existing ones. Introduction of the preparation after surgical removal of the primary tumor reduced lungs metastases volume (in 3.4 times) on the latter stages of investigation, but it did not influence on metastases number, at the same time on the early stages – metastasis process activation occurred in some particular cases.

The investigations, conducted on the transplantable tumor models - Gu-rin's carcinoma and sarcoma 45, showed that Amitozyn revealed antitumor action provided by its long-term introduction. Significant enhancement of Amitozyn effect was registered, on conditions that it was used together with local microwave hyperthermia.

It is illustrated in the experiment that Amitozyn is able to reduce toxic effect of chemical preparation platydiam at the same time increasing its antitumor effect.

It was determined that after Amitozyn introduction, endocrine thymus function, serum interferon level and big granulocytic lymphocytes (BGL) number enhanced, neutrophils number significantly increased.

Toxic influence of the preparation on the animal's organism was not determined.

Clinical trials on Amitozyn preparation use in oncological patients' treatment showed that almost all the patients have satisfactory reaction on the preparation. Amitozyn has no side effects, except for pyrogenic reaction that some of the patients had (temperature increasing on 0,5°C – 2°C). During 24 hours, the temperature becomes normal, at that, the patients who had temperature increasing reaction on the preparation introduction have higher Amitozyn

efficiency. After Amitozyn intake the most patients felt better state of health, appetite, the intensity of clinical disease signs reduction.

Amitozyn, depending on the malignant process localization, can lead to its stabilizing, partial regression, both a primary tumor, and metastases and full regression (in case of benign tumors and soft tissue sarcomas).

Moreover, Amitozyn application in the oncological patients' treatment significantly depends on indications and contraindications to its use, the number of courses and single and course doses size. It is also determined that treatment efficiency of the patients with malignant neoplasms increases in case of simultaneous use Amitozyn preparation with chemical radiation therapy. Mainly, it may be specified by Amitozyn immunomodulatory effect (by increasing the lymphocytes, neutrophils, T-lymphocytes, T-helpers number, BGL level, IgG and IgM), it also induces endogenous interferon and thymic serum hormone creation.

Thus, the conducted researches showed that Amitozyn reveals certain antitumor activity without side effect, which the most antitumor chemical preparations have. Furthermore, Amitozyn has positive effect on immune system of the animals and people.

It is advisably to recommend for Pharmacological Committee to examine a question of Amitozyn official registration.