

**Assessment of immunomodulating effects of
alkylglycerols in healthy volunteers.**

Clinical Study, Moscow 1997

Juri Reznikov M.D., Ph.D.



**Head of Laboratory of Clinical Immunology Central
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Medical Centre of the Administration of the President of
the Russian Federation - Moscow, Russia.**

Marcin Krotkiewski M.D., Ph.D.



**Department of Rehabilitation Medicine, University of
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Introduction

Alkylglycerols have been described as immunological stimulators and used in treatment and / or prevention of cancer as well as prevention of myelosuppressive effects of cancer radiotherapy, preventing the leucopenia and thrombocytopenia following this kind of treatment.

More specifically, it has been shown that alkylglycerols activate haemopoiesis, enhance phagocytic and tumoricidal activity of neutrophils and macrophages / monocytes by activating production of reactive oxygen species in these cells, promote antitumour activity of NK-cells, elevate IgM and IgG levels in serum, inhibits expression of adhesive molecules on endothelial cells and last but not least - induce apoptosis of tumour cells (1,2,3,4,5,6,7)

The aim of the proposed pilot study is to further elucidate the possible mechanism of action of alkylglycerols by investigating their effects on the immune system in healthy volunteers.

Methods

Subjects

twenty-four healthy volunteers - men and women - were randomly divided into two groups. All volunteers have been subjected to usual medical examination. Neither medical examination nor medical history revealed any cardiovascular, kidney, pulmonary or infection diseases. Blood formula and serum biochemistry (AST, ALT, cholesterol, glucose) were normal. All participants were free from any medical treatment during the last 2 months preceding the tests.

Study design

A cross-over, double-blind placebo-controlled study design was used. The overall study design was approved by the Ethical Committee of the Central Clinical Hospital of the Medical Center of the Presidents Administration of Russian Federation.

All the participants signed a written informed consent in which all the main points of the study design as well as any possible side effects were mentioned.

Double-blind were done according to usual rules, i.e. both *Alkymer* and *Placebo* capsules had the same appearance and were packed in coded boxes.

