

A New Cytoprotective Drug on the Basis of Cytisine: Phase I Clinical Trial Results

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Abstract : Cytisine aminophosphonate under the name "Cytafat" was approved for clinical trials in Republic of Kazakhstan as a putative liver protecting drug for the treatment of acute toxic hepatitis. A method of conducting the clinical trial is a double blind study. Total number of patients -71, aged from 16 to 56 years. Research on healthy volunteers determined the maximal tolerable doze of "Cytafat" as 200 mg/kg. Side effects when administered at high dozes (100-200 mg/kg) are tachycardia and increase of arterial blood pressure. The drug is tested in the treatment of 28 patients with a syndrome of hepatocellular failure (a poisoning with substitutes of alcohol, rat poison, or medical products). "Cytafat" was intravenously administered at a dose of 10 mg/kg in 200 ml of 5 % glucose solution once daily. The number of administrations: 1-3. In the comparison group, 23 patients were treated intravenously once a day with "Essenciale H" at a dose of 10 ml. 20 patients received a placebo (10 ml of glucose intravenously). In all cases of toxic hepatopathology the significant positive clinical effect of the testing drug distinguishable from placebo and surpassing the alternative was observed. Within a day after administration a sharp reduction of cytolytic syndrome parameters (ALT, AST, alkaline phosphatase, thymol turbidity test, GGT) was registered, a reduction of the severity of cholestatic syndrome (bilirubin decreased) was recorded, significantly decreased indices of lipid peroxidation. The following day, in all cases the positive dynamics was determined with ultrasound study (reduction of diffuse changes and events of reactive pancreatitis), hepatomegaly disappeared. Normalization of all parameters occurred in 2-3 times faster, than when using the drug "Essenciale H" and placebo. Average term of elimination of toxic hepatopathy when using the drug "Cytafat" -2,8 days, "Essenciale H" -7,2 days, and placebo -10,6 days. The new drug "Cytafat" has expressed cytoprotective properties.

Keywords : cytisine, cytoprotection, hepatopathy, hepatoprotection

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