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THE RESULT OF CLINICAL TRIAL FOR THE NEW LONAL DRUG FOR HEPATOPROTECTIVE EFFECT IN PATIENT WITH DRUG INDUCED STEATOSIS: A RANDOMIZED PLACEBO-CONTROLLED DOUBLE BLIND CLINICAL TRAIL

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Introduction: Following researchers determined the chronic hepatitis C virus infection which was 8,2% (Davaalkham.J et al, 2003), 9,6%(Takahashi.M et al, 2004), 9,8% (Tsatsralt-Od.B et al, 2006), 11,8% (Dagvadorj.Ya et al 2005) in Mongolia. As researchers noted that hepatitis C genotype 1 and 3 enable to be triglyceride accumulation for liver because it often occurs simultaneously fatty liver disease. Although many types of traditional medicine have been used for for hundreds years, their effectiveness of the therapy is relatively small with inadequate use of poorly understood in practice. These types of medicine's storage, form, flavor are to improve which are prepared based on scientific studying, is to make the clinical trial of drug acts as easily use, emerged as one of the need for market. Therefore, our research team has made the clinical trial based on the chemical and pharmacological study of hepatoprotective effect for lonicera altaica pall fruit, an established clinical studies and producing new drugs.

Aim: The aim of the clinical trial was to determine hepatoprotective effect of the new lonal drug in patient with fatty liver disease with chronic hepatitis C.

Material and Method: The research was considered such as clinical trial guideline for new drug issued by the WHO's "Good Clinical Practice". Based on permission given by biomedical ethical community of the health ministry of Mongolia approved diagnosis patient with fatty liver disease associated with chronic hepatitis C. Research design is randomized placebo-controlled, double blind clinical trial. We studied 3 groups of participants that was given the following treatment for 21 days: (I) Treatment group: Lonal drug 1.4 gr ×3 times, (II) Control group: Silymarin drug 67.5 mg ×3 times, (III) Placebo group: Placebo drug 1.4 gr ×3 times. We used on histo-morphometric analysis of liver biopsy DISKUS ver 4.80, Olympus BX microscopy.

Results: Lonal drug decreases activation of syndrome hepatic cell cytolysis ALT (p=0.023), AST (p=0.037). Also decreases criteria of cholestasic syndrome such as indirect bilirubin (p=0.611), ALP (p=0.04), GGT (p=0.445). The Lonal medicine was taken during 21 days and comparing the results of lipid metabolism exchange before and after treatment, reduces TG (p=0,402), increases HDL (p=0.047). The participants have taken the Fibroscan analysis and liver biopsy. That was compared to determine before and after treatment such as steatosis and fibrosis degree. Before treatment degree of steatosis was S2: 278.4±75.3 dB/m and after treatment it was dropped from S1: 238.6±70.4 dB/m (p <0.05). And before treatment, such as fibrosis degree F2-3: 8.84 ± 2.2 kPa, after treatment it was decreased in F1-2: 7.18 ± 3.87 (p<0.01). In liver histology, comparing before and after treatment the results of liver cell inflammation-fibrosis area was reduced by 1,75 times and decreases hepatic steatosis degree (strong fatty change was improved mild fatty change).

Conclusion: New lonal medicine is reducing activation syndrome hepatic cell cytolysis, cholestatic and some criteria of the metabolic syndrome in patient with fatty liver disease associated with chronic hepatitis C. Also new lonal medicine reduces the degree of liver steatosis and fibrosis by the analysis of fibroscan and liver biopsy.

Key Words: Fibroscan, liver biopsy, Lonicera Altaica Pall, Lonal.

BIOGRAPHY

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