**Research Paper**

**Research & Review: A Journal of Oncology & Haematology**

**ISSN: 2319–3387**

**Volume: 10, Year: 2021, Issue:3**

**Received date: 21 October 2021/ Accepted date: 11 November 2021/ Published date: 20 November 2021.**

**Biochemical analysis of unani formulation UNIM 104 in cases of Fatty Liver**

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**Abstract**

Fatty liver is one of the most important problems of the world when people have started having fast food, aerated drinks, alcohol and sedentary life style. In this there is deposition of fat in the hepatocytes, There are many medications available in the market for treating fatty liver , here in this study safety of unani pharmacopeial formulations UNIM 104 in patients of fatty liver was studied. For this blood samples were collected from fatty liver cases, they were subjected to biochemical analysis. Biochemical analysis show increase as well as decrease in their values, which are in normal range, this show that the unani formulation UNIM 104 is safe for consumption and free from toxic effects, so it can be used as a alternate medicine for treating fatty liver.

**Keywords: Fatty Liver, UNIM 104, LFT, KFT, Fat deposition.**

**Introduction**

Fatty liver develops when your body produces too much fat or doesn’t metabolize fat efficiently enough. The excess fat is stored in liver cells, where it accumulates and causes fatty liver disease (1). This build-up of fat can be caused by a variety of things like [drinking too much alcohol](https://www.healthline.com/health/alcohol-use-and-abuse) can cause alcoholic fatty liver disease. This is the first stage of [alcohol-related liver disease](https://www.healthline.com/health/alcoholism/liver-disease). In people who don’t drink a lot of alcohol, the cause of fatty liver disease is less clear (2). In many cases, fatty liver causes no noticeable symptoms. But you may feel tired or experience discomfort or pain in the abdomen. Some people with fatty liver disease develop complications, including liver scarring. Liver scarring is known as [liver fibrosis](https://www.healthline.com/health/liver-fibrosis). If you develop severe liver fibrosis, it’s known as [cirrhosis](https://www.healthline.com/health/cirrhosis).

 Cirrhosis is potentially life-threatening condition which may cause symptoms such as [loss of appetite](https://www.healthline.com/health/appetite-decreased) ,[weight loss](https://www.healthline.com/symptom/unintentional-weight-loss), [weakness,](https://www.healthline.com/symptom/asthenia) [fatigue,](https://www.healthline.com/symptom/fatigue) nose bleeding, itchy skin, yellow skin of eyes, web like clusters of blood vessels under your skin, abdominal pain and swelling, swelling in legs , breast enlargement in men and confusion (3).  There are many factors that play an important role in fatty liver this includes obesity, high blood sugar, insulin resistance, high levels of fat especially triglycerides in blood. While less common causes include pregnancy, rapid weight loss, some type of infection such as hepatitis C, side effect from some medications like methotrexate and tamoxifen and valproic acid, exposure to certain toxins, certain genes also increase the risk of developing fatty liver. To diagnose fatty liver, your doctor will take your medical history, conduct a physical exam and order one or more tests (4).

 If your doctor suspects that you might have fatty liver, they will likely to ask you questions about your family medical history, including any history of liver disease, alcohol consumption and other lifestyle habits, medical conditions that you might have any medications that you might take recent changes in your health. To check for liver inflammation, your doctor may palpate or press on your abdomen. If your liver is [enlarged](https://www.healthline.com/symptom/liver-enlarged), they might be able to feel it. This was an open trial for 2 years, patients in this were enrolled for three months duration in allotted group UNIM 104 (5 gms Majoon daily semi solid preparation). The patients were registered as per inclusion criteria. Follow up was done after every 15 days and investigations were done after one month and after completion of the trial. During the reporting period 45 cases were registered.

 Fatty liver occurs when too much fat builds up in liver cells. Normally tiny fat is found in liver but if it is more than 5 % it is called fatty liver. Major risk factors include obesity, type 2 diabetes and excessive alcohol consumption. Its treatment involves reducing the risk factors such as obesity by controlling diet and exercise programme. In a few cases fatty liver can progress to liver failure (cirrhosis). Fatty liver is also known as hepatic steatosis. It happens when fat builds up in the liver. Having small amounts of fat in your liver is normal, but too much can became a health problem. Liver is the second largest organ in your body, it helps process nutrients from food and drinks and filters harmful substances from young blood. In many cases, fatty liver disease is diagnosed after blood tests show elevated liver enzymes.

 For example, your doctor may order the [alanine aminotransferase test](https://www.healthline.com/health/alt) (ALT) and [aspartate aminotransferase test](https://www.healthline.com/health/ast) (AST) to check your liver enzymes. These tests might be recommended if you’ve developed signs or symptoms of liver disease, or they might be ordered as part of [routine blood work](https://www.healthline.com/health/blood-tests). Elevated liver enzymes are a sign of liver inflammation. Fatty liver disease is one potential cause of liver inflammation, but it’s not the only one. If you test positive for elevated liver enzymes, your doctor will likely order additional tests to identify the cause of the inflammation. Imaging studies are also performed for fatty liver this includes ultrasound, CT and MRI scan.

 Liver biopsy is one of the best way to determine severity of liver disease (like fatty liver and its scarring), in this doctor insert needle in liver and remove tissue for the examination, during this local anesthethia is given. Till today there is no medication available for fatty liver, in many cases life style modifications advised by the doctor which includes avoiding alcohol, steps to lose weight and make changes in diet. There are many home remedies as well which includes losing weight, reduce alcohol intake, and eat nutrient rich diet, daily exercise. According to the [Mayo Clinic](https://www.mayoclinic.org/diseases-conditions/nonalcoholic-fatty-liver-disease/diagnosis-treatment/drc-20354573), some evidence suggests that vitamin E supplements might help prevent or treat liver damage caused by fatty liver disease. However, more research is needed. There are some [health risks](https://www.healthline.com/health/all-about-vitamin-e) associated with consuming too much vitamin E. Always talk to your doctor before you try a new supplement or natural remedy. Some supplements or natural remedies might put stress on your liver or interact with medications you’re taking.

**Study Objective:**

To assess the safety of Unani Pharmacopeial formulations UNIM 104 in patients of Fatty Liver.

**Methodology:**

This study was done in laboratory of Regional Research Institute of Unani Medicine, New Delhi. The study was carried out, to investigate safety (Laboratory Parameters) of Unani pharmacopeial formulation UNIM 104 in cases of Fatty liver. In this study, 45 cases in the age group of 18-60 years, presenting sign and symptom with fatty liver were taken. Patients with pregnancy, taking long term treatment like Diabetes mellitus etc and oral contraceptives were excluded from the study. Follow up was done after every 15 days and investigations were done after one month and after completion of the trial.

 No concomitant medication was allowed during the study, for assessing safety of the unani formulation following laboratory investigations were performed:

* + LFT (S. Bilirubin, SGOT, SGPT, S Alkaline phosphatase)
	+ KFT ( S. Creatinine, S.Urea)

Laboratory investigations were performed at baseline and at end of study. Statistical analysis was done using Students ‘T’ test. Biochemical data at the baseline and at the end of the study was analysed using Student T test. Significance level of P < 0.05 was used in this study.

**Blood Collection**

Blood samples were collected by puncturing the vein at each investigation. 3.0 ml of blood sample was allowed to clot and serum was separated by centrifugation, which was used for various biochemical parameters. Biochemical investigations were carried out on fully automatic analyser EM -200 (Transasia).

***Biochemical Analysis***

 Estimation of Serum glutamate pyruvate transaminase ( SGPT ) and Serum glutamate oxaloactete transaminase (SGOT) was done according to the method described by International Federation of Clinical Chemistry (IFCC) (Bradley et.al.,) (5) while on the other hand estimation of Serum alkaline phosphatase (S-ALP) was done by IFCC kinetic method (6), Bilirubin by end point diazo method (7), Blood urea by GLDH-urease initial rate method (8) , Creatinine by Jaffes initial rate method (9) and Uric acid by modified Trinder (10) end point method was used.

**Dose and administration**

The patients were enrolled for three months duration in the allotted group, patients were given UNIM 104 orally (5 gms Majoon daily semi solid preparation).The patients were registered as per inclusion criteria. Follow up was done after every 15 days and investigations were done after one month and after completion of the trial.

**Observation**

***Biochemical studies***

Fatty liver is the most common problem in the developing and developed world. There are many allopathic medications available in the market but this study has been designed to study safety parameter of unani formulation UNIM 104 in cases fatty liver. Post medication there is decrease in Total cholesterol, Triglyceride, HDL, Urea, Creatinine, Bilirubin, OT, PT, ALP, TPR and Alb.

**Table 1- Post medication changes in Lipid profile, LFT and KFT**

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **S.No** | **T.Cho** | **Tg** | **HDl** | **LDL**  | **Urea** | **Creat** | **T.Bil** | **OT** | **PT** | **ALP** | **TPR** | **Alb** |
| **Pre** | 211*±*34 | 157.9*±*70.4 | 56.7*±* 22 | 129.4*±*38 | 28.0*±* 8.8 | 0.83*±*0.17 | 0.74*±* 0.3 | 50.6*±*28.4 | 53.8*±*29.5 | 134.9*±* 66.9 | 8.2*±*1.90 | 5.26*±*0.7 |
| **Post** | 200.2*±*46.6 | 138.2*±*45.7 | 55.3*±*9.8 | 129.4*±*27.5 | 24.0*±*3.1 | 0.80*±*0.17 | 0.56*±*0.23 | 35.57*±*26.4 | 37.6*±*20.19 | 122.19*±*38.24 | 7.72*±* 0.7 | 5.20*±*0.56 |
| **P -Value** | **0.013** | **0.00** | **0.78** | **0.23** | **0.6** | **0.19** | **0.01** | **0.001** | **0.001** | **0.031** | **0.910** | **0.86** |

This increase or decrease are in normal range, therefore it can be inferred that this formulation (UNIM 104) did not induce any negative response which confirms safety of this drug (Table 1).

**Result and discussion**

This study was done at Regional Research Institute of Medical Sciences, New Delhi. In this persons from both the sexes having fatty liver were registered, biochemical investigations were done to see toxic effect of the unani formulation UNIM 104, it has been seen that values of liver and kidney function test were in normal limits which show that this unani formulation is free from side effects and is safe for human consumption.

**Conclusion**

There are many allopathic medicines available in the market for fatty liver which have some or the other side effect, nowadays people around the world are shifting towards the herbal formulation which show minimal side effect on long run .Keeping this in mind, a trial was conducted on fatty liver cases with unani formulation UNIM 104 and it has been found safe for human consumption.

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