

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of Wheat Germ consumption on anthropometric indices, lipid profiles, glycemic status, hepatic enzymes, hepatocyte apoptosis (Cytokeratin-18), inflammatory factors, total antioxidant capacity and liver fibrosis in non-alcoholic fatty liver patients

#### Protocol summary

Hepatic fibrosis, and steatosis Lipid profile, Glycemic indices, Liver enzymes, Inflammatory factors

#### Study aim

The effect of Wheat Germ consumption on anthropometric indices, lipid profiles, glycemic status, hepatic enzymes, hepatocyte apoptosis (Cytokeratin-18), inflammatory factors, total antioxidant capacity and liver fibrosis in non-alcoholic fatty liver patients

#### Design

Randomized clinical trials with control groups, parallel group are performed on 42 patients

#### Settings and conduct

In this study, adults with non-alcoholic fatty liver disease referred to liver clinic of Taleghani hospital, who have the criteria to enter the study, if they desire to participate in this research fill out general and activity questionnaires and anthropometric indicators are collected. At the beginning and end of the study, fibroscan and blood tests are performed to evaluate the indicators

#### Participants/Inclusion and exclusion criteria

People who desire to participate in the study; age 18-50 years; BMI above 25 who have evidence of non-alcoholic steatohepatitis in ultrasound or fibroscan; no history of alcohol consumption or alcohol consumption less than 10 grams per day in women and less than 20 grams per day in men; absence of other chronic and acute liver diseases and disorders, biliary tract disease, autoimmune diseases, cancer and hereditary disorders affecting Liver status and liver cirrhosis, lack of pregnancy or lactation in women; no use of hepatotoxic drugs are included in the study. If they do not want to continue studying or using hepatotoxic drugs during the study or non-compliance with the diet, they are excluded.

#### Intervention groups

1- Control 2-wheat germ

#### Main outcome variables

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20100524004010N32**

Registration date: **2020-11-07, 1399/08/17**

Registration timing: **prospective**

Last update: **2020-11-07, 1399/08/17**

Update count: **0**

##### Registration date

2020-11-07, 1399/08/17

##### Registrant information

##### Name

Azita Hekmatdoost

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences,  
National Institute of Nutrition Research

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2293 0824

##### Email address

hekmat@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-11-21, 1399/09/01

##### Expected recruitment end date

2021-09-23, 1400/07/01  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
The effect of Wheat Germ consumption on anthropometric indices, lipid profiles, glycemic status, hepatic enzymes, hepatocyte apoptosis (Cytokeratin-18), inflammatory factors, total antioxidant capacity and liver fibrosis in non-alcoholic fatty liver patients

**Public title**  
The effect of Wheat Germ consumption on anthropometric indices, lipid profiles, glycemic status, hepatic enzymes, hepatocyte apoptosis, inflammatory factors, total antioxidant capacity and liver fibrosis in non-alcoholic fatty liver patients

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

General desire to participate in the study Age 50-30 years Has evidence of non-alcoholic steatohepatitis and CAP score more than 263 Body mass index (BMI)  $\geq 25$ kg / m<sup>2</sup> No history of alcohol consumption Lack of other diseases and chronic and acute liver disorders (hepatitis B, C, etc.), biliary disease, known autoimmune diseases and hereditary disorders affecting the condition of the liver (iron, copper and ... ) No pregnancy or breastfeeding in women Do not take hepatotoxic drugs such as phenytoin, amoxifen and lithium Do not take antibiotics for more than a week during or before the study period Do not consume Milk thistle(Silybum marianum) Lack of chronic inflammatory disease No history of cancer Lack of treatment with anti-inflammatory drugs Lack of recent weight loss diet Do not use weight loss drugs (chemical drugs and effective herbal products)

**Exclusion criteria:**

Changes in medications (lipid-lowering drugs, blood sugar control drugs, and blood pressure medications) during the study period Lack of adherence to the intervention given to patients Take supplements or substances that change the individual effect during the intervention

**Age**  
From **18 years** old to **60 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **50**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**

The first step is to create a random sequence number. For this purpose, we will use a random number generator on Stattrek (<https://stattrek.com/statistics/random-number-generator.aspx>) for 50 numbers range from 1 to 2 (for example: 2 1 1 2 1 2 1 1 2 2 1 1 2 2 2 11 1 2 2 1 1 2 2.....). Then, we will specify the numbers to the groups for example, 1 will be assigned to the intervention group one (wheat germ), the numbers 2 to the control group. Each number will represent a group according to the defined numbers. With this method, we will have a specific sequence of 50 codes of 1, 2, which shows the first to fifty people who are going to be entered in the study in each group. We write the codes on a piece of paper and put them in an envelope to use during sampling. Thus, after reviewing the inclusion criteria and if the participants desire, we will enter each person included in the study according to our predetermined list.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics Committee of the National Institute of Nutritional Research and Food Industry

**Street address**

No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town

**City**

tehran

**Province**

Tehran

**Postal code**

1981619573

**Approval date**

2020-10-24, 1399/08/03

**Ethics committee reference number**

IR.SBMU.NNFTRI.REC.1399.045

**Health conditions studied**

1

**Description of health condition studied**

Nonalcoholic fatty liver disease

**ICD-10 code**

K75.81

## ICD-10 code description

Nonalcoholic steatohepatitis (NASH)

## Primary outcomes

### 1

#### Description

Hepatic steatosis, Liver fibrosis

#### Timepoint

At the first and at the 12th week of the study

#### Method of measurement

fibroscan

## Secondary outcomes

### 1

#### Description

Weight

#### Timepoint

At the first and 12th week of the study

#### Method of measurement

Scale

### 2

#### Description

BMI

#### Timepoint

At the first and 12th week of the study

#### Method of measurement

Calculate

### 3

#### Description

liver enzymes (AST,ALT,GGT)

#### Timepoint

At the first and 12th week of the study

#### Method of measurement

Enzymatic method

### 4

#### Description

lipid profile (TG,Total cholesterol,LDL-C,HDL-C)

#### Timepoint

At the first and 12th week of the study

#### Method of measurement

Enzymatic method

### 5

#### Description

hs-CRP

#### Timepoint

At the first and 12th week of the study

#### Method of measurement

ELISA

## Intervention groups

### 1

#### Description

Intervention group: wheat germ

#### Category

Lifestyle

### 2

#### Description

Control group: bread crumbs

#### Category

Lifestyle

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Gastroenterology and Liver Clinic of Taleghani Hospita

##### Full name of responsible person

Azita Hekmatdoost

##### Street address

Tabnak St. Velenjak Region, Chamran High Way, Tehran, Iran

##### City

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##### Province

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##### Postal code

1985717413

##### Phone

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a\_hekmat2000@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Azita Hekmatdoost

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No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town

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**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
No  
**Title of funding source**  
Research Assistant Shahid Beheshti University of Medical Sciences  
**Proportion provided by this source**  
100  
**Public or private sector**  
Public  
**Domestic or foreign origin**  
Domestic  
**Category of foreign source of funding**  
*empty*  
**Country of origin**  
**Type of organization providing the funding**  
Academic

## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Azita Hekmatdoost  
**Position**  
Assistant Professor  
**Latest degree**  
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**Other areas of specialty/work**  
Nutrition  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

### Contact

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

### Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

### Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

### Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

### Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

### Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

### Data Dictionary

Undecided - It is not yet known if there will be a plan to

make this available