Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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

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

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

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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) ≥ 25kg / m2 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 1 2 1 2 1 1 2 2 1 1 2 2 2 2 11 1 2 2 1 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
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Tabnak St. Velenjak Region, Chamran High Way, Tehran, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
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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 updating data

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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