

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### therapeutic Effect and safety of squill oxymel in control of fatty liver disease in patients with mild to moderate fatty liver

#### Protocol summary

##### Summary

Fatty liver is a problem that is seen in 2 percent of the general population and 20% of liver biopsies that are prepared for various causes. Today, different treatment ways are used in patients with fatty liver, some of which, such as metformin, is elected according to the nature of pathophysiological conditions associated with metabolic syndrome, and others like ursodeoxy colic acid (ursodiol) with the aim of removing of accumulating fat from liver. Meanwhile, some medications, such as vitamins and herbal medicines due to their antioxidant properties are considered for therapy. One of the herbal remedies based on traditional medicine may be effective in treating fatty liver, is extract of squill that due to the antioxidant and anti-inflammatory properties may be effective as a supplement.in traditional iranian medicine (TIM),squill (drimia maritima) oxymel was utilized in the treatment of liver disease.Accordingly, it was decided in this study to evaluate the effectiveness of squill syrup be addressed in the treatment of fatty liver In this study, which is done as a placebo controlled trial ,150 patients with fatty liver were selected that refer to Hospital Baqiyatallah in 1395. After filling out a written consent, the patients randomly divided to two groups of 75, receiving placebo syrup or squill syrup and treated for two months. Meanwhile the patients under study,take routine drugs included metformin 500 (twice a day) and vitamin E (at a rate of 800 iu / day) too. both intervention and control groups, before the start of the study and after completion of treatment,have to do ultrasound of the liver,evaluation of serum levels of liver enzymes, AST and ALT and ALP, and the results in between the two groups will be compared

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201705261165N20**

Registration date: **2017-07-23, 1396/05/01**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-07-23, 1396/05/01

##### Registrant information

###### Name

Yunes Panahi

###### Name of organization / entity

Baqiyatallah University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8821 1524

###### Email address

yunespanahi@bmsu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

baqiatallah hospital

##### Expected recruitment start date

2017-04-21, 1396/02/01

##### Expected recruitment end date

2018-03-11, 1396/12/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

therapeutic Effect and safety of squill oxymel in control of fatty liver disease in patients with mild to moderate fatty liver

**Public title**

Effect of squill oxymel in control of mild to moderate fatty liver

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

Inclusion criteria: To Sign the consent form Knowingly patients be suffered from mild to moderate fatty liver According to the ultrasound result. Exclusion criteria: Off treatment for more than a week Progression of Fatty liver disease Person is pregnant or lactating Allergic reactions to herbal blend

**Age**

From **18 years** old to **75 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **150**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features**

simple randomized

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of the Islamic Azad University of Pharmaceutical Science

**Street address**

Islamic Azad University of Pharmaceutical Science; Yasaman alley; Yakhchal street; Doctor shariatie; Tehran; Iran

**City**

tehran

**Postal code****Approval date**

2010-08-20, 1389/05/29

**Ethics committee reference number**

ir.iau.ps.rec.1394.35

**Health conditions studied****1****Description of health condition studied**

fatty liver

**ICD-10 code**

k76.0

**ICD-10 code description**

k75.8

**Primary outcomes****1****Description**

improvement of quality of life

**Timepoint**

at baseline and 2 month after intervention

**Method of measurement**

quality of life questionnaire

**2****Description**

FBS

**Timepoint**

at baseline and 2 month after intervention

**Method of measurement**

mg/dl

**3****Description**

triglycerides

**Timepoint**

at baseline and 2 month after intervention

**Method of measurement**

mg/dl

**4****Description**

cholesterol

**Timepoint**

at baseline and 2 month after intervention

**Method of measurement**

mg/dl

**5****Description**

hdl

**Timepoint**

at baseline and 2 month after intervention

**Method of measurement**

mg/dl

**6****Description**

ldl

**Timepoint**

at baseline and 2 month after intervention

**Method of measurement**

mg/dl

## 7

### Description

alt

### Timepoint

at baseline and 2 month after intervention

### Method of measurement

iu/l

## 8

### Description

ast

### Timepoint

at baseline and 2 month after intervention

### Method of measurement

iu/l

## 9

### Description

alp

### Timepoint

at baseline and 2 month after intervention

### Method of measurement

iu/l

## 10

### Description

grade of fatty liver

### Timepoint

at baseline and 2 month after intervention

### Method of measurement

sonography

## Secondary outcomes

### 1

#### Description

bmi

#### Timepoint

at baseline and 2 month after intervention

#### Method of measurement

kg/m2

## Intervention groups

### 1

#### Description

intervention:squill oxymel,scientific name:drimia maritima. each 5 ml contains 25 mg of squill. dose of consumption:30 ml daily (orally).devided 3 times a day. duration of consumption:2 month. gorgan-niak-co

#### Category

Treatment - Drugs

## 2

### Description

control:placebo oxymel,15 cc daily,until 2 month

### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

digestion clinic,baqiatallah hospital

##### Full name of responsible person

Dr yuns panahi

##### Street address

Nosrati Ave., South sheykhbahee St., Mollasadra St.

##### City

tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research Baqiyatallah University of medical sciences

##### Full name of responsible person

dr yunes panahi

##### Street address

Nosrati Ave., South sheykhbahee St., Mollasadra St.

##### City

tehran

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Vice chancellor for research Baqiyatallah University of medical sciences

#### Proportion provided by this source

100

#### Public or private sector

empty

#### Domestic or foreign origin

empty

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

empty

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

pharmaceutical sciences branch islamic azad university

##### Full name of responsible person

fateme hadei

**Position**

doctorate of pharmacy

**Other areas of specialty/work**

**Street address**

Islamic Azad University of Pharmaceutical Science;  
Yasaman alley; Yakhchal street; Doctor shariatie;  
Tehran; Ira

**City**

tehran

**Postal code**

**Phone**

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**Fax**

**Email**

yunespanahi@yahoo.com

**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

chemical injuries reaserch center,baqiatallah  
university of medical sciences

**Full name of responsible person**

dr yunes panahi

**Position**

clinical pharmacist

**Other areas of specialty/work**

**Street address**

Nosrati Ave., South sheykhbahee St., Mollasadra St.

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**Web page address**

**Person responsible for updating data**

**Contact**

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*