

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Aug 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	
<u>7</u>	
Description	alt
Timepoint	at baseline and 2 month after intervention
Method of measurement	iu/l
<u>8</u>	
Description	ast
Timepoint	at baseline and 2 month after intervention
Method of measurement	iu/l
<u>9</u>	
Description	alp
Timepoint	at baseline and 2 month after intervention
Method of measurement	iu/l
<u>10</u>	
Description	grade of fatty liver
Timepoint	at baseline and 2 month after intervention
Method of measurement	sonography
Secondary outcomes	
<u>1</u>	
Description	bmi
Timepoint	at baseline and 2 month after intervention
Method of measurement	kg/m2
Intervention groups	
<u>1</u>	
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

<u>2</u>	
Description	control:placebo oxymel,15 cc daily,until 2 month
Category	Placebo
Recruitment centers	
<u>1</u>	
Recruitment center	
Name of recruitment center	digestion clinic,baqiataallah hospital
Full name of responsible person	Dr yuns panahi
Street address	Nosrati Ave., South sheykhbahaae St., Mollasadra St.
City	tehran
Sponsors / Funding sources	
<u>1</u>	
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 sheykhbahaae 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;
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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

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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