

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Comparison of the effect of silymarin and placebo on serum liver enzyme level in patients with trauma in the Intensive Care Unit in Rajaei hospital

Protocol summary

Study aim

Comparison of the effect of silymarin and placebo on serum liver enzyme level in trauma patients with increased liver enzyme level in the Intensive Care Unit.

Design

Double-blind, randomized, parallel-group, placebo-controlled clinical trial

Settings and conduct

This study will be conducted in the ICU of Rajaei hospital, Shiraz, Iran. Trauma patients who have elevated liver enzymes will be categorized into two groups by permuted block randomization: 1. Receiving livergol 2- Receiving Placebo. Every patient will be determined by a number and the list of numbers of patients in each group will be given to the nurses. The participants, the physicians, the investigator and the data collectors will be blinded to the study.

Participants/Inclusion and exclusion criteria

Input criteria include: People aged 16 or over Not taking a known hepatotoxic drug Silymarin Not taking oral silymarin during the past day No confirmed history of allergic reactions following oral administration of silymarin Increased ALT and AST levels Not taking concomitant antioxidants or compounds such as vitamin A, C, E and N-acetyl cysteine. Oral tolerance to medications Exclusion criteria : Pregnancy or lactation History of advanced liver disease

Intervention groups

Treatment group: Trauma patients in intensive care units with elevated liver enzymes who receive silymarin.
Control group: Trauma patients in intensive care units with elevated liver enzymes who receive placebo.

Main outcome variables

Liver enzyme levels

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190911044744N1**

Registration date: **2019-09-22, 1398/06/31**

Registration timing: **prospective**

Last update: **2019-09-22, 1398/06/31**

Update count: **0**

Registration date

2019-09-22, 1398/06/31

Registrant information

Name

Ehsan Mirzaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 1820 5885

Email address

ehsan.mirzaei.1369@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-11, 1398/07/19

Expected recruitment end date

2020-05-08, 1399/02/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of silymarin and placebo on serum liver enzyme level in patients with trauma in the Intensive Care Unit in Rajaei hospital

Public title

The effect of silymarin on serum liver enzyme level in patients with trauma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

People aged 16 or over Not taking a known hepatotoxic drug Not taking oral silymarin during the past day No confirmed history of allergic reactions following oral administration of silymarin Alanine aminotransferase (ALT) levels more than 2-fold above normal (> 70 IU / L) up to 4-fold above normal Or aspartate aminotransferase (AST) levels more than 2-fold above normal (> 70 IU / L) up to 4-fold above normal Not taking concomitant antioxidants or compounds such as vitamin A, C, E and N-acetyl cysteine Oral tolerance to medications

Exclusion criteria:

Pregnancy or lactation History of advanced liver disease

Age

From **16 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Method of randomization: Permuted block randomization. The patients are divided into 18-person groups. Using the statistical software, 9 out of 18 patients are randomly assigned to treatment group and 9 to placebo group. Unit of randomization: Individual. Tools used in randomization: computer software.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the participants, the principle investigator, the physicians and the data collectors are blinded. The patients who are going to receive the drug or placebo , are determined by numbers and these numbers are given to the head nurse and nurses of the ICU.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Shiraz school of pharmacy, Karafarin street, Roknabad Town

City

Shiraz

Province

Fars

Postal code

71468 64685

Approval date

2019-08-23, 1398/06/01

Ethics committee reference number

IR.SUMS.REC.1398.768

Health conditions studied

1

Description of health condition studied

Liver Trauma

ICD-10 code

S36.112

ICD-10 code description

Contusion of liver

Primary outcomes

1

Description

Decreased liver enzyme levels

Timepoint

Start of study, end of first week, end of second week

Method of measurement

Blood test

2

Description

Measurement of free radicals

Timepoint

The beginning and the end of the study

Method of measurement

Blood test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Receiving Livergol tablet 140 mg Goldaru factory orally every eight hours for 14 days yo

reduce liver enzyme levels

Category

Treatment - Drugs

2

Description

Control group: Receiving placebo which was prepared in pharmaceutical laboratory of Shiraz School of Pharmacy in similar to livergol tablet in size and color orally every eight hours for 14 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rajaei hospital

Full name of responsible person

Afsaneh Vazin

Street address

Shiraz school of pharmacy, Karafarin street, Roknabad Town

City

Shiraz

Province

Fars

Postal code

713451583

Phone

+98 71 3242 4127

Email

Vazeena@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Younes Ghasemi

Street address

Shiraz University of Medical Sciences, Zand Blvd.

City

Shiraz

Province

Fars

Postal code

71345-1978

Phone

+98 71 3235 7282

Email

vcrdep@sums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Ehsan Mirzaei

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Clinical pharmacy

Street address

Shiraz school of pharmacy, Karafarin Street, Roknabad Town

City

Shiraz

Province

Fars

Postal code

713451583

Phone

+98 71 3242 4127

Email

ehsan.mirzaei.1369@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Ehsan Mirzaei

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Clinical pharmacy

Street address

Shiraz school of pharmacy, Karafarin Street, Roknabad Town

City

Shiraz

Province

Fars
Postal code
713451583
Phone
+98 71 3242 4127
Email
ehsan.mirzaei.1369@gmail.com

713451583
Phone
+98 71 3242 4127
Email
ehsan.mirzaei.1369@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Ehsan Mirzaei
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Clinical pharmacy
Street address
Shiraz school of pharmacy, Karafarin Street,
Roknabad Town
City
Shiraz
Province
Fars
Postal code

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