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 Rajaee 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 nvestigator 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 witch 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

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713451583

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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.

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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

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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