Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparative effect of Silimarina (Livergo) with placebo on liver enzymes in patients taking Isotretinoin

Protocol summary

Summary

The aim of this study was to check impact of Silimarina (Livergo) on liver enzymes in patients taking Isotretinoin. Inclusion criteria included: Acne; treatment with isotretinoin and aged between 15 -50.Exclusion criteria included: Liver disease; history of alcohol use; pregnancy and sensitivity to Livergo. This is a double-blind clinical trial. 70 patients with acne that consumer isotretinoin were divided into two groups randomly, intervention (n=35) and control (n=35) groups. At baseline, levels of liver enzyme were measured. Then, 140 mg Livergol capsules daily were given to the intervention group for 30 days. Also Starch capsules daily were given to the intervention group for 30 days. The liver enzymes were measured after study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016080814229N5**
Registration date: **2016-09-02, 1395/06/12**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-09-02, 1395/06/12

Registrant information

Name

Hadi Jafari manesh

Name of organization / entity

Arak University of Medical Science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2017-03-21, 1396/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative effect of Silimarina (Livergo) with placebo on liver enzymes in patients taking Isotretinoin

Public title

Effect of Silimarina (Livergo) on liver enzymes in patients taking Isotretinoin

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria included: Acne; treatment with isotretinoin; aged between 15 -50 and Consent to participate in research. Exclusion criteria included: Liver disease; history of alcohol use; pregnancy and sensitivity to Livergo.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double 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 Arak University of Medical Sciences

Street address

Basij Sq. Arak

City

Arak

Postal code

3819693345

Approval date

2015-03-01, 1393/12/10

Ethics committee reference number

93-175-17

Health conditions studied

1

Description of health condition studied

آکنه

ICD-10 code

L70.0

ICD-10 code description

Acne vulgaris

Primary outcomes

1

Description

Alanine Transaminase

Timepoint

Before and after 30 days

Method of measurement

U/L - Laboratory kit

2

Description

Aspartate transaminase

Timepoint

Before and after 30 days

Method of measurement

U/L - Laboratory kit

3

Description

Alkaline Phosphatase

Timepoint

Before and after 30 days

Method of measurement

U/L - Laboratory kit

Secondary outcomes

empty

Intervention groups

1

Description

Group 1 (intervention): 140 mg Livergol capsules daily for 30 days

Category

Treatment - Drugs

2

Description

Group 2 (control):Starch capsules daily for 30 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital

Full name of responsible person

Hadi Jafari Manesh

Street address

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Davood Hekmatpou

Street address

Basij Sq. Arak
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Arak
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak 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

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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