

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 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)

Phone

+98 86 3417 3503

Email address

jafarimanesh@arakmu.ac.ir

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 Livregol 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

City

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

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Hadi Jafari Manesh

Position

Master of Nursing

Other areas of specialty/work

Street address

Basij Sq. Arak

City

Arak

Postal code

Phone

+98 86 3417 3503

Fax

Email

nurse_science@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Hadi Jafari Manesh

Position

Master of Nursing

Other areas of specialty/work

Street address

Basij Sq. Arak

City

Arak

Postal code

Phone

+98 86 3417 3503

Fax

Email

nurse_science@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Hadi Jafari Manesh

Position

Master of Nursing

Other areas of specialty/work

Street address

Basij Sq. Arak

City

Arak

Postal code

Phone

+98 86 3417 3503

Fax

Email

Web page address

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