Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of Silybum marianum on methotrexate-induced hepatotoxicity and its analgesic effect in the patients with rheumatoid arthritis history

Protocol summary

Study aim

The effect of Silybum marianum on methotrexate-induced hepatotoxicity and its analgesic effect in the patients with rheumatoid arthritis history

Design

Patients will be randomly divided into intervention and control groups (30 patients in each group). The study will be Double-blind and with parallel groups .The intervention group consisted of rheumatoid arthritis patients who received 280 mg of oral silymarin daily for 2 months.The control group consisted of rheumatoid arthritis patients who received of placebo tablets the shape and packaging are quite similar to Silymarin daily for 2 months.

Settings and conduct

The study will be conducted in the Rheumatology units of Amir al-Momenin hospitals. The study will be Double-blind and with parallel groups .The intervention group consisted of rheumatoid arthritis patients who received 280 mg of oral silymarin daily for 2 months.The control group consisted of rheumatoid arthritis patients who received of placebo tablets the shape and packaging are quite similar to Silymarin daily for 2 months.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 1-Age between 16 and 85 2-No history of liver disease 3-taking methotrexate 4- Diagnosis of rheumatoid arthritis with criteria American Collage of Rhematology Exclusion Criteria: 1-Abnormal liver function tests at admission 2- Dissatisfaction of the patient 3- Pregnancy and lactation

Intervention groups

The intervention group consisted of rheumatoid arthritis patients who received 280 mg of oral silymarin daily for 2 months.The control group consisted of rheumatoid arthritis patients who received placebo tablets the shape and packaging are quite similar to Silymarin daily for 2 months.

Main outcome variables

The impact of Silybum marianum on methotrexate-induced hepatotoxicity and its analgesic effect in the patients with rheumatoid arthritis history patients will be assessed.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180519039711N4**
Registration date: **2020-02-04, 1398/11/15**
Registration timing: **prospective**

Last update: **2020-02-04, 1398/11/15**
Update count: **0**

Registration date

2020-02-04, 1398/11/15

Registrant information

Name

Mohamad Golitaleb

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3506

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-20, 1398/12/01

Expected recruitment end date

2022-02-20, 1400/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Silybum marianum on methotrexate-induced hepatotoxicity and its analgesic effect in the patients with rheumatoid arthritis history

Public title

Effect of silymarin on the liver and pain of rheumatoid arthritis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 16 and 85 No history of liver disease taking methotrexate Diagnosis of rheumatoid arthritis with criteria American Collage of Rhematology

Exclusion criteria:

Unwilling to continue studying Discharge or death of the patient Sensitivity to methotrexate

Age

From **16 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly divided into intervention and control groups. Sixty patients were randomly assigned to either the intervention or control groups, initially 6 blocks of 10 different T and C letters (which represent the intervention and control groups) (30) from the intervention group and 30 from the intervention group. People belong to the control group). Then, the blocks were randomly selected to obtain a 60-sided combination of blocks. It opens to tell which group the patient falls into.

Blinding (investigator's opinion)

Double blinded

Blinding description

Clinical caregivers, data analysts, and patients are not aware of being in the control or intervention group.

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

Deputy of Education and Research,Campus University of Medical Sciences site,Basij square,Arak

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3848176941

Approval date

2019-09-24, 1398/07/02

Ethics committee reference number

IR.ARAKMU.REC.1398.130

Health conditions studied

1

Description of health condition studied

Rheumatoid arthritis

ICD-10 code

M05

ICD-10 code description

Rheumatoid arthritis with rheumatoid factor

Primary outcomes

1

Description

درد

Timepoint

Before and 60 Day after intervention

Method of measurement

Visual Analogue Scale

2

Description

Hepatotoxicity

Timepoint

Before and 60 Day after intervention

Method of measurement

check list

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Take daily with oral 280-mg Silymarin For 2 months

Category

Treatment - Drugs

2

Description

Control group: Control group take under the administration of placebo

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Amiralmomenin Hospital

Full name of responsible person
Mohamad Golitaleb

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
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Grant name

Grant code / Reference number

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

No

Title of funding source
Arak 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
Arak University of Medical Sciences

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Position
nursing student

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Bachelor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
The information will be published in the final report and article.

When the data will become available and for how long
The information will be published in the final report and article.

To whom data/document is available
The information will be published in the final report and article.

Under which criteria data/document could be used
The information will be published in the final report and article.

From where data/document is obtainable
The information will be published in the final report and article.

What processes are involved for a request to access data/document
The information will be published in the final report and article.

Comments