

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

The effects of licorice supplementation on clinical symptoms and inflammatory markers in patients with active rheumatoid arthritis

Protocol summary

Study aim

Determining the effect of licorice supplementation on clinical symptoms and inflammatory markers in patients with active rheumatoid arthritis

Design

Intervention group: Rheumatoid arthritis patients who received capsules containing 0.5 mg of licorice prepared by Iran Daruk Company 3 times a day for 8 weeks.
Control group: Rheumatoid arthritis patients receiving capsules containing placebo, prepared by Iran Daruk Company, receive orally 3 times a day for 8 weeks. by statistical consultant and by software

Settings and conduct

The upcoming research plan will be a simple randomized allocation and double-blind clinical trial that will be conducted on known rheumatoid arthritis patients under the treatment of a specialist doctor at the Sirjan Faculty of Medical Sciences clinic. Patients will participate in this project after obtaining written informed consent and meeting the inclusion criteria.

Participants/Inclusion and exclusion criteria

The study inclusion criteria include patients with rheumatoid arthritis aged between 20 and 70 years. Also, the exclusion criteria will include the following: heart, kidney or hypertension patients, history of heart attack, high blood lipids, abnormal kidney or liver function, use of non-steroidal anti-inflammatory drugs, use of vitamins and/or supplements minerals and drugs such as thyroid hormones, antihypertensive drugs, contraceptives, diuretics and beta blockers

Intervention groups

Intervention group: Rheumatoid arthritis patients who received capsules containing 0.5 mg of licorice prepared by Iran Daruk Company 3 times a day for 8 weeks.
Control group: Rheumatoid arthritis patients receiving capsules containing placebo, prepared by Iran Daruk Company, receive orally 3 times a day for 8 weeks.

Main outcome variables

Disease activity score 28

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221127056629N1**

Registration date: **2022-12-18, 1401/09/27**

Registration timing: **prospective**

Last update: **2022-12-18, 1401/09/27**

Update count: **0**

Registration date

2022-12-18, 1401/09/27

Registrant information

Name

Mohammad amin Serpoosh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 4223 2052

Email address

ma.serpoosh@sirums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-22, 1401/10/01

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of licorice supplementation on clinical symptoms and inflammatory markers in patients with active rheumatoid arthritis

Public title

The effect of licorice administration on patients with rheumatoid arthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with joint rheumatism referring to Sirjan Faculty of Medical Sciences clinic Filling the consent form by patients

Exclusion criteria:

Heart, kidney or hypertension patients, history of heart attack, high blood lipids, abnormal kidney or liver function, use of non-steroidal anti-inflammatory drugs, use of vitamins and/or mineral supplements and drugs such as thyroid hormones, anti-hypertensive drugs Blood, contraceptives, diuretics and beta-blockers, as well as alcohol consumption, smoking, pregnancy and breastfeeding Other underlying diseases and also it should be mentioned that each person participating in the study will be excluded from the study in case of discontinuation of treatment or side effects caused by the consumption of licorice.

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **76**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly divided into two groups of intervention (38 patients) and placebo (38 patients). Supplement and placebo will be placed in similar containers by someone outside the study based on the corresponding codes written on the containers. Supplement or placebo recipients will be assigned based on entry code. In this double-blind study, the factors that can distort the results of the experiment, such as information about receiving a supplement or placebo, will remain hidden from both the participants (patients) and the researcher.

Blinding (investigator's opinion)

Double blinded

Blinding description

Supplement and placebo will be placed in similar containers by someone outside the study based on the corresponding codes written on the containers. Supplement or placebo recipients will be assigned based on entry code. In this double-blind study, the factors that can distort the results of the experiment, such as

information about receiving a supplement or a placebo, will remain hidden from both the participants (patients) and the researcher.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

کمیته اخلاق دانشکده علوم پزشکی سیرجان

Street address

Ibn Sina St., Sirjan school of Medical Sciences

City

sirjan

Province

Kerman

Postal code

7816916338

Approval date

2022-11-19, 1401/08/28

Ethics committee reference number

IR.SIRUMS.REC.1401.012

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

Disease severity

Timepoint

0,90

Method of measurement

Disease activity score 28 (DAS28)

Secondary outcomes

1

Description

Erythrocyte sedimentation rate

Timepoint
0,90
Method of measurement
Westergren method

2

Description
intensity of pain

Timepoint
0,90

Method of measurement
The patients will be asked to mark their pain level from their point of view on a ten-point scale.

3

Description
CRP

Timepoint
0,90

Method of measurement
Agglutination method

4

Description
TNF- α

Timepoint
0,90

Method of measurement
Eliza method

5

Description
IL-6

Timepoint
0,90

Method of measurement
Eliza method

6

Description
Systolic blood pressure

Timepoint
0,90

Method of measurement
by barometer

7

Description
diastolic blood pressure

Timepoint
0,90

Method of measurement
by barometer

8

Description
AST

Timepoint
0,90
Method of measurement
Colorimetric method and photometer

9

Description
licorice

Timepoint
0,90

Method of measurement
by scales

10

Description
potassium

Timepoint
0,90

Method of measurement
Flynn photometry method

11

Description
fasting blood sugar

Timepoint
0,90

Method of measurement
Colorimetric method and photometer

Intervention groups

1

Description
Intervention group: Rheumatoid arthritis patients who received capsules containing 0.5 mg of licorice prepared by Iran Daruk Company 3 times a day for 8 weeks.

Category
Treatment - Drugs

2

Description
Control group: Rheumatoid arthritis patients receiving capsules containing placebo, prepared by Iran Daruk Company, receive orally 3 times a day for 8 weeks.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

درمانگاه دانشکده علوم پزشکی سیرجان

Full name of responsible person

دکتر محمود رضا مسعودی

Street address

Ibn Sina Street - Sirjan Faculty of Medical Sciences
City
sirjan
Province
Kerman
Postal code
7816916338
Phone
+98 34 4223 4513
Email
Masoodi85@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
sirjan school of medical science
Full name of responsible person
Dr mahmood reza masoudi
Street address
خیابان ابن سینا
City
sirjan
Province
Kerman
Postal code
7816916338
Phone
+98 34 4223 4513
Email
Masoodi85@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
sirjan school of medical science
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
sirjan school of medical science
Full name of responsible person
Mohammad amin serpoosh
Position
faculty member
Latest degree

Master
Other areas of specialty/work
Physiology
Street address
ibn sina street , sirjan school of medical science
City
sirjan
Province
Kerman
Postal code
7816916338
Phone
+98 34 4223 4513
Email
aminsrps@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
sirjan school of medical science
Full name of responsible person
Dr mahmood reza masoudi
Position
faculty member
Latest degree
Subspecialist
Other areas of specialty/work
Rheumatology
Street address
ibn sina street sirjan school of medical science
City
sirjan
Province
Kerman
Postal code
7816916338
Phone
+98 34 4223 4513
Email
Masoodi85@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
sirjan school of medical science
Full name of responsible person
Mohammad amin serpoosh
Position
faculty member
Latest degree
Master
Other areas of specialty/work
Physiology
Street address
ibn sina street , sirjan school of medical science
City
sirjan
Province
Kerman

Postal code

7816916338

Phone

+98 34 4223 4513

Email

aminsrps@gmail.com

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