

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

Effect of Grape seed (Grapex medicine) on improvement and relief of disease activity and severity in patients with Rheumatoid Arthritis

Protocol summary

Study aim

Study of the effect of Grape seed (Grapex) on improvement and relief of disease activity and severity in patients with Rheumatoid Arthritis

Design

This is a controlled double-blind clinical trial study conducted on 60 patients with Rheumatoid arthritis. Patients (N= 30 per group) were randomly treated with Grapex or placebo for 8 weeks.

Settings and conduct

This clinical trial study was conducted on 60 rheumatoid arthritis patients with moderate to severe disease activity referring to Golestan Hospital in Ahvaz in 2017-18. Patients were randomly treated with Grapex (100 mg daily) or placebo (100 mg daily) for 8 weeks. The disease activity and severity was evaluated base on Modified DAS28 score.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 18 years, consent to participate in the study, patients with rheumatoid arthritis based on ACR 2010 criteria, moderate to severe disease activity based on Modified DAS28 score; Exclusion criteria: Duration of diseases more than 5 years, concomitant use of warfarin, allergy to grapes and its components, presence of any type of malignancy and cancer, pregnancy.

Intervention groups

Treatment with Grapex (100 mg) or placebo

Main outcome variables

Activity and severity of disease, ESR and CRP, tender joint count (TJC), swollen joint count (SJC)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180212038705N3**

Registration date: **2018-07-24, 1397/05/02**

Registration timing: **retrospective**

Last update: **2018-07-24, 1397/05/02**

Update count: **0**

Registration date

2018-07-24, 1397/05/02

Registrant information

Name

Fariba Heidari

Name of organization / entity

Country

Iran (Islamic Republic of)

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heidari.p@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-11, 1396/09/20

Expected recruitment end date

2018-03-11, 1396/12/20

Actual recruitment start date

2017-12-16, 1396/09/25

Actual recruitment end date

2018-03-11, 1396/12/20

Trial completion date

empty

Scientific title

Effect of Grape seed (Grapex medicine) on improvement and relief of disease activity and severity in patients with Rheumatoid Arthritis

Public title

Effect of Grapex on patients with Rheumatoid Arthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age over 18 years
Consent to participate in the study
Patients with rheumatoid arthritis based on ACR 2010 criteria
Moderate to severe disease activity based on Modified DAS28 score

Exclusion criteria:
Duration of diseases more than 5 years
Concomitant use of warfarin
Allergy to grapes and its components,
Presence of any types of malignancy and cancer
Pregnancy

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were randomly assigned into two groups.
Assignment of patients to the study groups was done by block randomization method using four blocks.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patients were unaware of the drug they were receiving (Grapex or placebo). Also the experimenters did not know about type of treatment and patient grouping and thus until the end of trial the study remained double-blinded.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur university of medical sciences

Street address

Jundishapur university of medical sciences, Golestan Blvd., Ahvaz

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Approval date

2017-10-04, 1396/07/12

Ethics committee reference number

IR.AJUMS.REC.1396.893

Health conditions studied

1

Description of health condition studied

Rheumatoid arthritis

ICD-10 code

M06.9

ICD-10 code description

Rheumatoid arthritis, unspecified

Primary outcomes

1

Description

Disease severity

Timepoint

At baseline and after treatment (8 week)

Method of measurement

Modified DAS28 score

2

Description

Erythrocyte sedimentation rate (ESR)

Timepoint

At baseline and after treatment

Method of measurement

Western Green analysis

3

Description

Swollen joint count (SJC)

Timepoint

At baseline and after treatment

Method of measurement

Examination and clinical judgment of the physician

4

Description

Tender joint count (TJC)

Timepoint

At baseline and after treatment

Method of measurement

Examination and clinical judgment of the physician

5

Description

CRP

Timepoint

At baseline and after treatment

Method of measurement

Agglutination test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Grapex 100 mg daily

Category

Treatment - Drugs

2

Description

Control group: placebo 100 mg daily

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Hospital

Full name of responsible person

Dr. Elham Rajaei

Street address

Golestan Hospital, Farvardin Ave., Golestan

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6135733118

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Badavi

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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Elham Rajaei

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Rheumatology

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Person responsible for scientific inquiries

Contact

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Ahvaz University of Medical Sciences

Full name of responsible person

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Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Ddaruish Mokaramian

Position

Internal Medicine Residency

Latest degree

Medical doctor

Other areas of specialty/work

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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