

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Study of efficacy and safety of suranjafel in patients with rheumatoid arthritis

Protocol summary

Study aim

In this study we aim to evaluate the efficacy of suranjafel in clinical manifestation and laboratory parameters in patients with active rheumatoid arthritis in intervention group compared with placebo . in this study we also evaluate and analyze safety and adverse reaction of this drug.

Design

a phase 3 , randomized , double-blinded clinical trial in two parallel groups . 88 patients are entered in this study . blocking method with dice is used for randomizing .

Settings and conduct

In this study 88 patients with active rheumatoid arthritis based on inclusion and exclusion criteria referred from shahid beheshti hospital will be admitted . patients will randomly divided to control and intervention group and take drug and placebo twice a day for three month in parallel (each pill contains 125 milligram of substance) . DAS28 questionnaire and ACR20/50/70 criteria are assessed monthly and interleukin6 and other blood tests are performed at the beginning and at the end of study and then are analyzed at the end . this study is performing blindly and the patient , physician and researcher do not know whether the patient is receiving medication or placebo.

Participants/Inclusion and exclusion criteria

patients with active rheumatoid arthritis who are between 18-65 years old and were diagnosed more than 3 month ago and are not pregnant or breastfeeding and do not suffer from serious medical condition like diabetes mellitus , cardiovascular disease and severe hepatic or renal dysfunction .

Intervention groups

intervention group : the group of patients who take the pill twice a day for three month control group : the group with same condition who take the placebo

Main outcome variables

clinical manifestation based on DAS28 questionnaire :
improving symptoms based on ACR 20/50/70 criteria :

interleukin6

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211214053400N1**

Registration date: **2021-12-26, 1400/10/05**

Registration timing: **registered_while_recruiting**

Last update: **2021-12-26, 1400/10/05**

Update count: **0**

Registration date

2021-12-26, 1400/10/05

Registrant information

Name

Farzane Heidari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2209 0351

Email address

heidariifarzane@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-20, 1400/09/29

Expected recruitment end date

2022-06-19, 1401/03/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Study of efficacy and safety of suranjafel in patients with rheumatoid arthritis

Public title
Study of efficacy and safety of suranjafel in patients with rheumatoid arthritis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 patients with active rheumatoid arthritis patients who are diagnosed more than 3 months ago patients with BMI less than 40
Exclusion criteria:
 chronic diseases like diabetes mellitus , cardiovascular disease and severe hepatic or renal disfunction patients who got drug reaction pregnancy and breastfeeding

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **88**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization. We will have 4 blocks of 6 and the selection of each block will be random and we use dice each time.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study participants, physicians and researchers are not aware whether they get drug or placebo.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Qum University of Medical

Sciences

Street address

Qum University of Medical Science , Shahid Lavasani Street , Qum

City

Qum

Province

Ghoum

Postal code

3713649373

Approval date

2021-10-26, 1400/08/04

Ethics committee reference number

IR.MUQ.REC.1400.144

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

Clinical activity of disease based on disease activity score 28 questionnaire (DAS28)

Timepoint

At the beginning of the study and then one month , two month and three month later

Method of measurement

Disease activity score 28 questionnaire (DAS28)

2

Description

Measure of improvement of patient clinical manifestation based on ACR regular 2010 criteria

Timepoint

At the beginning of the study and then one month , two month and three month later

Method of measurement

ACR regular 2010 criteria

3

Description

The level of interleukin6

Timepoint

At the beginning and the three month later at the end of study

Method of measurement

Blood test

Secondary outcomes

1

Description

The level of erythrocyte sedimentation rate

Timepoint

At the beginning and then at the end of study

Method of measurement

Blood test

2

Description

The level of c-reactive protein

Timepoint

At the beginning and then at the end of study

Method of measurement

Blood test

3

Description

The level of Rheumatoid Factor

Timepoint

At the beginning and then at the end of study

Method of measurement

Blood test

Intervention groups

1

Description

Intervention group:

Category

Treatment - Drugs

2

Description

Control group:

Category

Placebo

Recruitment centers

1

Recruitment center**Name of recruitment center**

Shahid Beheshti Hospital

Full name of responsible person

Farzane Heidari

Street address

Shahid beheshti Blvd , Qum

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Web page address

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Ghoum University of Medical Sciences

Full name of responsible person

Ehsan sharifipour

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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

bouali Pharmaceutical Company

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Industry

Person responsible for general inquiries

Contact**Name of organization / entity**

Ghoum University of Medical Sciences

Full name of responsible person

Farzane Heidari

Position

medical intern

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

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Person responsible for updating data

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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