Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 suranjefel 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 interlukin6 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 wheter the patient is receiving mediv=cation 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 ore breastfeeding and do not suffer from serious medical condition like diabetes mellitus , cardiovascular disease and severe hepatic or renal disfunction .

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 ؛ interlukin6

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 interlukin6
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 syudy
Method of measurement
Blood test

2

Description
The level of c-reactive protein
Timepoint
At the beginning and then at the end of syudy
Method of measurement
Blood test

3

Description
The level of Rheumatoid Factor
Timepoint
At the beginning and then at the end of syudy
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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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 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