Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Evaluation the effect of DHEA (dehydroepiandrosterone) on quality of life and disease activity in women with Rheumatoid Arthritis

Protocol summary

Summary

This is a randomized, double-blind, placebo-controlled clinical trial aimed to investigate the effect of dehydroepiandrosterone (DHEA) on quality of life and disease activity in 46 women with rheumatoid arthritis. Inclusion criteria are pre-menopause women, having a definitive diagnosis of rheumatoid arthritis and a normal BMI and exclusion criteria are having other chronic diseases, hyperlipidemia and using anti-depressants. After inclusion in the study, in all patients, disease activity will be assessed using DAS-28 score and also quality of life will be evaluated using WHO questionnaire. Then, the patients will be randomly assigned into two equal groups; DHEA group who will receive the drug as 50 mg oral tablets once a day for three months and the placebo group who will receive placebo. At the end of the treatment period, the disease activity and quality of life will be evaluated again and the data

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017052134062N1**
Registration date: **2017-07-23, 1396/05/01**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-07-23, 1396/05/01

Registrant information

Name

Elnaz Langarizadeh

Name of organization / entity

Zahedan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Zahedan University of Medical Sciences

Expected recruitment start date

2017-06-22, 1396/04/01

Expected recruitment end date

2017-08-23, 1396/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of DHEA (dehydroepiandrosterone) on quality of life and disease activity in women with Rheumatoid Arthritis

Public title

The effect of dehydroepiandrosterone on quality of life

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: pre-menopause women; having a definitive diagnosis of rheumatoid arthritis; having a normal BMI. Exclusion criteria: having other chronic diseases; hyperlipidemia; using anti-depressants.

Age

From **45 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Randomization and blinding: Firstly, the resident will select 46 patients based on inclusion and exclusion criteria and introduce them to an educated nurse. The nurse will randomly, by using permuted block randomization, assign the patients into DHEA and placebo groups and register their names and the allocated group and then will write the names of patients of DHEA group on the DHEA drugs boxes and the names of patients of placebo group on the placebo boxes and will give the boxes to the resident to deliver the boxes to the patients; therefore, the resident is blinded (DHEA drugs and placebo boxes have a similar appearance). Considering that the boxes have a similar appearance, the patients are also blinded (When giving a written consent, it will be explained to the patients that for improving the accuracy of the results, the patients should be blinded but they are either in DHEA or placebo group. The cons and pros of each treatment option will be explained).

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zahedan University of Medical Sciences

Street address

Zahedan University of Medical Sciences and Health Services campus, Khalije Fars Blv, Doctor Hesabi Sq, Zahedan

City

Zahedan

Postal code

Approval date

2017-04-16, 1396/01/27

Ethics committee reference number

IR.ZAUMS.REC.1396. 7

Health conditions studied

1

Description of health condition studied

rheumatoid arthritis

ICD-10 code

M05

ICD-10 code description

Seropositive rheumatoid arthritis

Primary outcomes

1

Description

Disease activity

Timepoint

Before study, at the en of the study

Method of measurement

Using DAS-28 score

2

Description

Quality of life

Timepoint

Before study, at the en of the study

Method of measurement

Using WHO questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

DHEA group: 50 mg oral tablets once a day for three months

Category

Treatment - Drugs

2

Description

Placebo group: daily oral tablets containing starch for thee months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Ebne Abi Taleb Hospital

Full name of responsible person

Elnaz Langarizadeh

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Khalije Fars Blv, Zahedan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Zahedan University of Medical Sciences
Full name of responsible person
Hoshang Rafighdoost
Street address
Vice chancellor for research, Zahedan University of Medical Sciences campus, Jannat Blv, Zahedan
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Zahedan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Zahedan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty