

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 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)

###### Phone

+98 54 3329 5725

###### Email address

e.langarizadeh@zaums.ac.ir

###### 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 three 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

**City**  
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

#### Contact

**Name of organization / entity**  
Zahedan University of Medical Sciences

**Full name of responsible person**  
Elnaz Langarizadeh

**Position**  
Internal medicine resident

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

#### Contact

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Mahnaz Sandooghi

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Associate Professor

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## Person responsible for updating data

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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*