

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The effect of Conjugated linoleic acids on some bone markers, in adult with active rheumatoid arthritis referring to Shariaty Hospital Rheumatology research Centre. center

#### Protocol summary

##### Summary

This study will examine, the effect of Conjugated linoleic acids on some bone markers in patients with active RA, In a randomized, double-blind, placebo controlled clinical trial in shariati Hospital, 46 RA patients between 18-69 years old age with Active RA after Rheumatologist examination and filling personal, medical and food questionnaires will be enrolled in the study. They randomly will divide into 2 groups, each group will receive one of the following daily 2 capsules for 3 months; Group C: 2.5 gr glycerinated CLAs(50-50) daily, Group P: placebo 2.5 gr sunflower oil daily. Placebo capsules are completely similar to cases one and will divide randomly between Patients. Patients will be control weekly by calling and in the end of each month by visiting. Before and After the 3 months intervention period this test for comparing two groups will be done: PTH, Osteocalcine, telopeptide C were measured by ELISA method, and Ca by HPLC .

#### General information

##### Acronym

The effect of CLAs on some bone markers, in adult with active RA.

##### IRCT registration information

IRCT registration number: **IRCT201403029472N5**  
Registration date: **2014-03-19, 1392/12/28**  
Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2014-03-19, 1392/12/28

##### Registrant information

Name

Naheed Aryaeian

##### Name of organization / entity

Iran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8670 4750

##### Email address

aryaeian.n@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tehran University of Medical Sciences

##### Expected recruitment start date

2014-04-16, 1393/01/27

##### Expected recruitment end date

2014-10-22, 1393/07/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of Conjugated linoleic acids on some bone markers, in adult with active rheumatoid arthritis referring to Shariaty Hospital Rheumatology research Centre. center

##### Public title

The effect of Conjugated linoleic acids on some bone markers, in adult with active rheumatoid arthritis

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: person with RA diseases as ACR criteria, having RA from 2 years ago; age between 18-69

years; not being pregnant or lactated; not smoking and drink alcohol; haven't eaten multivitamin or antioxidants supplements from 3 month ago; don't eat lowering blood pressure; don't eat anti pregnancy drugs, exclusion criteria: Changes in diet or physical activity every day; taking less than 80% of supplements given to patients at baseline(the compliance lower than %80); consumption of contraceptives, multivitamins and antioxidant supplements; renal , hepatic , thyroid, parathyroid diseases, cancer, heart. diseases.

**Age**

From **18 years** old to **69 years** old

**Gender**

Both

**Phase**

1

**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****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Tehran university of medical sciences

**Street address**

Tehran University of Medical Sciences, Keshavarz Bld,  
Qods street

**City**

Tehran

**Postal code****Approval date**

2014-03-01, 1392/12/10

**Ethics committee reference number**

92-03-41-24528-107523

**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**

Telopeptide C

**Timepoint**

Before and after the study

**Method of measurement**

Bleeding and measurement with ELISA

**2****Description**

Osteocalcine

**Timepoint**

Before and after the study

**Method of measurement**

Bleeding and measurement with ELISA

**3****Description**

Serum PTH

**Timepoint**

Before and after the study

**Method of measurement**

Bleeding and measurement with ELISA

**4****Description**

Serum Calcium

**Timepoint**

Before and After the study

**Method of measurement**

Bleeding and measurement with HPLC

**Secondary outcomes****1****Description**

Nsaid usage

**Timepoint**

Before and after study

**Method of measurement**

Questionnair

**2****Description**

BMI

**Timepoint**

Before and after study

**Method of measurement**

Formula

## Intervention groups

### 1

#### Description

Intervention Group: Patients that refer to hospital shariatti have interval criteria and will receive CLAs supplement voluntarily and they receive daily 2\*1.25gr glycerinated CLAs(50-50) capsules for 3 months.

#### Category

Treatment - Other

### 2

#### Description

Control groups: Patients that refer to hospital shariatti have interval criteria and will receive placebo voluntarily and they receive daily 2\*1.25gr Sunflower capsules for 3 months.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Rhumatology research centre

##### Full name of responsible person

Farhad Shahram

##### Street address

Shariaty Hospital, Jalal Aleahmad Street

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice-chancellor for Research, Tehran University of Medical Sciences

##### Full name of responsible person

Mr Dr Masood Yonesian

##### Street address

Tehran University of Medical Sciences, Keshavarz Bld, Qods street

##### City

Tehran

#### 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, Tehran 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

Iran University of Medical Sciences

##### Full name of responsible person

Naheed Aryaeian

##### Position

assistant Professor/PhD in Nutrition

##### Other areas of specialty/work

##### Street address

Nutrition faculty, School of public health, Iran University of Medical Sciences, Hammat Bld.

##### City

Tehran

##### Postal code

##### Phone

+98 21 8670 4755

##### Fax

##### Email

aryaeian@razi.tums.ac.irnah\_arya2002@yahoo.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Iran University of Medical Sciences.

##### Full name of responsible person

Naheed Aryaeian

##### Position

assistant Professor/PhD in Nutrition

##### Other areas of specialty/work

##### Street address

Nutrition faculty, School of public health, Iran University of Medical Sciences, Hammat Bld.

##### City

Tehran

##### Postal code

##### Phone

+98 21 8670 4755

##### Fax

##### Email

nah\_arya2002@yahoo.comaryaeian@razi.tums.ac.ir

##### Web page address

## Person responsible for updating data

#### Contact

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Naheed Aryaeian

**Position**

assistant Professor/PhD in Nutrition

**Other areas of specialty/work**

**Street address**

Nutrition faculty, School of public health, Iran  
University of Medical Sciences, Hammat Bld.

**City**

Tehran

**Postal code**

**Phone**

+98 21 8670 4755

**Fax**

**Email**

aryaeian@razi.tums.ac.ir nah\_arya2002@yahoo.com

**Web page address**

## 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*