

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 shariaty 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

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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

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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