Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 between18-69 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 measurment with ELISA

2

Description
Osteocalcine

Timepoint
Before and after the study

Method of measurement
Bleeding and measurment with ELISA

3

Description
Serum PTH

Timepoint
Before and after the study

Method of measurement
Bleeding and measurment with ELISA

4

Description
Serum Calcium

Timepoint
Before and After the study

Method of measurement
Bleeding and measurment 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
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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
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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