

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of Ginger consumption on the some immunity and inflammatory mediators in adult with active Rheumatoid arthritis referingto Shariaty Hospital

Protocol summary

Summary

This study examined the effect of Ginger on some inflammatory and Immunity factors in patients with active RA referring to shariaty Hospital. In a randomized, double-blind, placebo -controlled clinical trial, 70 patients ,age between 18-69 years old with Active RA after Rheumatologist examination and filling personal, medical and food questionnaires will be enrolled in the study. They will be divided in 2 groups (35 numbers in each group) including: 1- Ginger (case) 2-Placebo (control) randomly. Patients in case group will receive 1500 mg of powdered Ginger daily (by two 750 mg capsules) for 3 months and control patients will receive 1500 mg Wheat flour daily (by two 750mg capsules) , one 750 mg capsule before lunch and one before dinner for 3 months. 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: DAS28, ESR, CRP, IL1 β , TNF α , IL17, IL2, IL4, IL10 in two groups will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201207109472N4**
Registration date: **2014-03-19, 1392/12/28**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-03-19, 1392/12/28

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences IRAN University of Medical Sciences

Expected recruitment start date

2014-03-11, 1392/12/20

Expected recruitment end date

2015-04-19, 1394/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Ginger consumption on the some immunity and inflammatory mediators in adult with active Rheumatoid arthritis referingto Shariaty Hospital

Public title

The effect of Ginger powder consumption on inflammation and Immunity in Rheumatoid arthritis disease

Purpose

Supportive

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: **35**

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, Research deputy

City

Tehran

Postal code

Approval date

2014-02-04, 1392/11/15

Ethics committee reference number

92-034122604-107079

Health conditions studied

1

Description of health condition studied

adult active Rheumatoid arthritis

ICD-10 code

M06.9

ICD-10 code description

Rheumatoid arthritis, unspecified

Primary outcomes

1

Description

hsCRP

Timepoint

Before and after intervention

Method of measurement

Elisa

2

Description

IL17

Timepoint

Before and after intervention

Method of measurement

ELISA

3

Description

TNFa

Timepoint

Before and after intervention

Method of measurement

ELISA

4

Description

IL10

Timepoint

Before and after treatment

Method of measurement

ELISA

5

Description

IL2

Timepoint

Before and after intervention

Method of measurement

ELISA

6

Description

DAS28

Timepoint

Before and after study

Method of measurement

using ESR,CRP and number of joints with inflammation.

7

Description

IL4

Timepoint

Before and after treatment

Method of measurement

ELISA

8

Description

ESR

Timepoint

Before and after the study

Method of measurement

Westergern method

Secondary outcomes

1

Description

BMI

Timepoint

Before and after intervention

Method of measurement

weight(kg)/height(m*2)

2

Description

Nsaiids intake

Timepoint

Before and after intervention

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention Group: Patients that refer to hospital shariatti have interval criteria and will receive Ginger voluntarily. Patients in case group will receive 1500 mg of powdered Ginger daily (by two 750 mg capsules) for 3 months ne 750 mg capsule before lunch and one before dinner for 3 months.

Category

Treatment - Other

2

Description

Control groups: Patients that refer to hospital shariatti have interval criteria and will receive starch or flour voluntarily. Patients in Control group will receive 1500 mg of wheat flour daily (by two 750 mg capsules) one 750 mg capsule before lunch and one before dinner 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, Aleahmad street.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research, Tehran University of Medical Sciences, Vice chancellor for Research, I

Full name of responsible person

Mr Dr Masood Yonesian, Mr Dr Motevalian

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Tehran University of Medical Sciences, Qods street, Keshavarz Bld

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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, Vice chancellor for Research, I

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

Nutrition faculty, Iran University of Medical Sciences

Full name of responsible person

Naheed Aryaeian

Position

assistant Professor/PhD in Nutrition

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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*