Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jul 2026

The effect of Ginger supplementation consumption on some genes expression that are mediators of immunity and inflammation in adult with active Rheumatoid Arthritis

Protocol summary

Summary

This study will examine the effect of Ginger on some inflammatory and Immunity Gene expression 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: The amout of Jene expression of NFkB، PPARγ، Foxp3، GATA3، T-bet, RORγ.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201403109472N6**
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

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

IRAN University of Medical Sciences

Expected recruitment start date

2014-03-11, 1392/12/20

Expected recruitment end date

2014-08-23, 1393/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Ginger supplementation consumption on some genes expression that are mediators of immunity and inflammation in adult with active Rheumatoid Arthritis

Public title

The effect of Ginger powder consumption on some genes expression that are mediators of immunity and inflammation in adult with Rheumatoid Arthritis

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
N/A

Groups that have been masked
No information

Sample size
Target sample size: **70**

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
Vice-chancellor for Research, Iran University of Medical Sciences

Street address
Hemmat Broadway

City
Tehran

Postal code

Approval date
2014-03-05, 1392/12/14

Ethics committee reference number
92-03-27-23598-100203

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
NFkB Jene expression amount

Timepoint
Before and after study

Method of measurement
PCR

2

Description
PPARγ Jene expression amount

Timepoint
Before and after study

Method of measurement
PCR

3

Description
Foxp3 Jene expression amount

Timepoint
Before and after study

Method of measurement
PCR

4

Description
GATA3 Jene expression amount

Timepoint
Before and after study

Method of measurement
PCR

5

Description
T-bet Jene expression amount

Timepoint
Before and after study

Method of measurement
PCR

6

Description
RORγ Jene expression amount

Timepoint
Before and after the study

Method of measurement
PCR

Secondary outcomes

1

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 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 - Drugs

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, Jalal Aleahmad Street
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for Research, Iran University of Medical Sciences
Full name of responsible person
Dr seid Ali Javad Mosavi
Street address
Vice-chancellor for Research, Iran University of Medical Sciences, Hammat Broadway
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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, Iran 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
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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