

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Ginger (*Zingiber officinale*) and turmeric supplementation effects on quality of life, bone mineral density, body composition and osteoporosis related biomarkers and micro-RNAs in women with postmenopausal osteoporosis

Protocol summary

Study aim

Determination of Ginger and turmeric supplementation effects on quality of life, body composition, bone mineral density and osteoporosis related bio-markers and micro-RNAs in women with postmenopausal osteoporosis

Design

This study is a randomized, triple-blind Phase 1 clinical trial in 120 women with postmenopausal osteoporosis. Participants will randomly be assigned into four groups.

Settings and conduct

The target population are all women with postmenopausal osteoporosis referred to the clinics of Tabriz University of Medical Sciences. Sampling will be done by convenience non randomized method. To conceal the allocation, the same envelope will be used in the opaque package to be numbered sequentially.

Participants/Inclusion and exclusion criteria

Inclusion criteria include natural menopause; age 45 and above; low bone density (Score T minus 2.5 and lower) and no history of fracture. Exclusion criteria include the use of birth control pills or steroids during the study; renal failure; metastatic bone disease; taking medications that affect bone metabolism other than taking calcium-D supplements and alendronate that are given to all subjects with the same dose

Intervention groups

Participants will be randomly divided into four groups to receive 1) Ginger supplement 2) Turmeric supplement 3) Ginger-Turmeric supplement and 4) Placebo. In group 1, one capsule of 1000 mg of ginger and two placebo of turmeric, in group 2, two capsules of 500 mg of turmeric and one placebo of ginger, in group 3, three capsules (two turmeric capsules and one ginger capsule), and Group 4 will receive three capsules of placebo.

Main outcome variables

Quality of life; body composition; osteocalcin; bone

mineral density; procollagen type 1 amino-terminal propeptide; carboxy-Terminal cross-linked telopeptides of type 1 collagen; miR422a; miR-133a; miR-21 and miR-503

General information

Reason for update

Adding bone mineral densitometry as a primary outcome Increase sample size to gain sufficient study power Add coagulation disorders as an exclusion criterion Modify duration of intervention Modify and update the recruitment start and end dates

Acronym

IRCT registration information

IRCT registration number: **IRCT20161022030424N3**
Registration date: **2018-04-29, 1397/02/09**
Registration timing: **prospective**

Last update: **2022-09-06, 1401/06/15**

Update count: **2**

Registration date

2018-04-29, 1397/02/09

Registrant information

Name

Neda Dolatkhan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3336 1928

Email address

dolatkhan@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-01, 1397/02/11

Expected recruitment end date

2018-12-30, 1397/10/09

Actual recruitment start date

2018-05-15, 1397/02/25

Actual recruitment end date

2018-10-15, 1397/07/23

Trial completion date

2019-03-01, 1397/12/10

Scientific title

Ginger (*Zingiber officinale*) and turmeric supplementation effects on quality of life, bone mineral density, body composition and osteoporosis related biomarkers and micro-RNAs in women with postmenopausal osteoporosis

Public title

Ginger (*Zingiber officinale*) and turmeric supplementation effects in osteoporosis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Natural menopause Age 45 and above Menstrual cessation for 12 consecutive months low bone density (Score T minus 2.5 and lower) No history of fracture

Exclusion criteria:

Use Contraceptive Pills or Corticosteroids During Study
Kidney disease or failure Metastatic bone disease Taking medications that affect bone metabolism other than taking calcium-D supplements or Alendronate that are given to all subjects with the same dose. Malignancy coagulation disorders

Age

From **45 years** old

Gender

Female

Phase

0

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **120**

Actual sample size reached: **115**

Randomization (investigator's opinion)

Randomized

Randomization description

For random allocation of study participants to study groups, computer software RAS (Random Allocation Software) will be used through 4 and 8 glass block and allocation ratio of 1: 1.

Blinding (investigator's opinion)

Triple blinded

Blinding description

For concealment of the allocation, the same envelopes

will be used in the opaque package to be numbered sequentially. Therefore, no participant, researcher, and statistical analyst will be aware of the type of intervention received. Envelopes will be numbered from 1 to 120. The first envelope will be given to the first person who will be included in the study and will continue to complete the sampling.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Regional Ethics Committee of Tabriz University of Medical Sciences

Street address

Vice Chancellor for Research, Tabriz University of Medical Sciences, Golgasht Str.

City

Tabriz

Province

East Azarbaijan

Postal code

5166614756

Approval date

2017-11-06, 1396/08/15

Ethics committee reference number

IR.TBZMED.REC.1396.720

Health conditions studied**1****Description of health condition studied**

Postmenopausal osteoporosis

ICD-10 code

M81.0

ICD-10 code description

Postmenopausal osteoporosis

Primary outcomes**1****Description**

Quality of life

Timepoint

Evaluating the quality of life at the beginning of the study (before the intervention) and 4 months after the intervention began

Method of measurement

The Menopause Specific Quality of Life Questionnaire

2

Description

Body composition

Timepoint

Evaluating the Body composition at the beginning of the study (before the intervention) and 4 months after the intervention began

Method of measurement

Body composition analyzer

3

Description

Bone mineral density

Timepoint

Measuring serum Bone mineral density at the beginning of the study (before the intervention) and 4 months after the intervention began

Method of measurement

Dual X-ray absorptiometry (DXA)

Secondary outcomes

1

Description

Osteocalcin

Timepoint

Measuring serum osteocalcin at the beginning of the study (before the intervention) and 4 months after the intervention began

Method of measurement

Biochemical assay

2

Description

Procollagen type 1 amino-terminal Propeptide

Timepoint

Measuring serum Procollagen type 1 amino-terminal Propeptide at the beginning of the study (before the intervention) and 6 months after the intervention began

Method of measurement

Biochemical assay

3

Description

Caboxy-Terminal cross-linked telopeptides of type 1 collagen

Timepoint

Measuring serum Caboxy-Terminal cross-linked telopeptides of type 1 collagen at the beginning of the study (before the intervention) and 4 months after the intervention began

Method of measurement

Biochemical assay

4

Description

miR-422a (micro-RNA)

Timepoint

Measuring serum miR-422a (micro-RNA) at the beginning of the study (before the intervention) and 4 months after the intervention began

Method of measurement

Biochemical assay

5

Description

miR-133a (micro-RNA)

Timepoint

Measuring serum miR-133a (micro-RNA) at the beginning of the study (before the intervention) and 4 months after the intervention began

Method of measurement

Biochemical assay

6

Description

miR-21 (micro-RNA)

Timepoint

Measuring serum miR-21 (micro-RNA) at the beginning of the study (before the intervention) and 4 months after the intervention began

Method of measurement

Biochemical assay

7

Description

MiR-503 (micro-RNA)

Timepoint

Measuring serum MiR-503 (micro-RNA) at the beginning of the study (before the intervention) and 4 months after the intervention began

Method of measurement

Biochemical assay

Intervention groups

1

Description

Intervention group: Vomigone tablets manufactured by Dinah's pharmaceutical company containing 470 ± 30 mg of standardized rhizome powdered of ginger (*Zingiber officinale*) twice-daily with a meal in addition Curcuma placebo tablets manufactured by Dinah's pharmaceutical company, which are in shape, size, taste, smell and other appearance characteristics, are quite similar to the curcuma tablet and are free of powdered and turmeric extract twice-daily with a meal for 4 months

Category

Treatment - Other

2

Description

Intervention group: Curcuma tablets manufactured by Dinah's pharmaceutical company containing 450 mg of turmeric rhizome and 50 mg of turmeric extract twice-

daily with a meal for 4 months in addition Vomigone placebo tablets manufactured by Dinah's pharmaceutical company, which are in shape, size, taste, smell and other appearance characteristics, are quite similar to the Vomigone tablet and are free of powdered ginger twice-daily with a meal for 4 months

Category

Treatment - Other

3**Description**

Intervention group: Vomigone tablets manufactured by Dinah's pharmaceutical company containing 470 ± 30 mg of standardized rhizome powdered of ginger (*Zingiber officinale*) twice-daily with a meal in addition Curcuma tablets manufactured by Dinah's pharmaceutical company containing 450 mg of turmeric rhizome and 50 mg of turmeric extract twice-daily with a meal for 4 months

Category

Treatment - Other

4**Description**

Control group: Vomigone placebo tablets manufactured by Dinah's pharmaceutical company, which are in shape, size, taste, smell and other appearance characteristics, are quite similar to the Vomigone tablet and are free of powdered ginger twice-daily with a meal in addition Curcuma placebo tablets manufactured by Dinah's pharmaceutical company, which are in shape, size, taste, smell and other appearance characteristics, are quite similar to the curcuma tablet and are free of powdered and turmeric extract twice-daily with a meal for 4 months

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Emam Reza hospital

Full name of responsible person

Neda Dolatkah

Street address

Golgasht Str., Azadi Ave.

City

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Phone

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Email

dolatkahn@tbzmed.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Abolghasem Jouyban

Street address

Vice Chancellor for Research (VCR), Third Floor, Central Building No. 2, Tabriz University of Medical Sciences, Golgasht Ave.

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ajouyban@hotmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Neda Dolatkah

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Neda Dolatkah

Position

Assistant Professor

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Neda Dolatkah

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available