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 postmenoposal 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 Dolatkhah

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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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 postmenoposal 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 Corticostroids 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 standarized 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 standarized 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 Dolatkhah

Street address

Golgasht Str., Azadi Ave.

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Phone

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Email

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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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5166614756

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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 Dolatkhah

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

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Full name of responsible person
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Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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Person responsible for updating data

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Assistant Professor

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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