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Efficacy of an organic pomegranate polyphenol complex (VIQUA®) in type 1 primary osteoporosis in post-menopausal women

Submission date
22/06/2023

Recruitment status
No longer recruiting

Registration date
07/07/2023

Overall study status
Completed

Last Edited
04/07/2023

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Osteoporosis is characterized by the decline of bone mass and microarchitecture, leading to increased fragility fractures. Though there are many types and causes, Oxidative stress and inflammatory reactions are major factors that induce osteoporosis by promoting bone resorption and inhibiting bone formation. Current treatment options for osteoporosis have limitations and side effects and there is a requirement for effective, safe, and natural supplements to reduce and prevent this condition. This study aims to evaluate a supplement called VIQUA®, a natural polyphenol complex with a high concentration of unique metabolites derived from organic pomegranate, sourced from a microbiome-rich biodynamic plantation, in postmenopausal women with osteoporosis.

Who can participate?
Healthy postmenopausal women aged between 45 and 70 years old

What does the study involve?
Participants will be randomly assigned to a once-daily supplement or a placebo/dummy supplement for 36 weeks. The study objectives included assessing changes in bone mineral density, bone turnover markers, and antioxidant and inflammatory markers over the 36-week period.

What are the possible benefits and risks of participating?
The results of this study will provide valuable insights into the potential benefits of VIQUA® in improving bone health in postmenopausal women. There is no known risk, no side effect was detected using the trial product.

Where is the study run from?
INNOVATION LABO Sciences Co., Ltd (Japan)

When is the study starting and how long is it expected to run for?
July 2021 to July 2023

Who is funding the study?
INNOVATION LABO Sciences Co., Ltd (Japan)

Who is the main contact?
Dr Yuki Ikeda, development@innovationlabo.com (Japan)

Contact information

Type(s)
Scientific

Contact name
Dr Yuki Ikeda

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IL-213678

Study information

Scientific Title
Double-blind, placebo-controlled clinical study to analyze the efficacy of an organic pomegranate polyphenol complex supplementation on bone mineral density, bone turnover markers, inflammatory status, and antioxidant status in post-menopausal women

Acronym
VIQOSTEO

Study objectives

VIQUA® increases bone mineral density, bone turnover markers, inflammatory status, and antioxidant status

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 08/02/2022, Japanese Society of Anti-Aging Nutrition (Ginza, Chuo-ku, Tokyo 6-6-1, 104-0061, Japan; +81 3 3552 5277; coordinator@jaan.jp), ref: ILOS210617-N713

Study design
Double-blind interventional randomized placebo-controlled trial

Primary study design
Interventional

Study type(s)
Quality of life, Treatment, Efficacy

Health condition(s) or problem(s) studied
Prevention of osteoporosis in postmenopausal women

Interventions
Subjects were randomly assigned in a 1:1 ratio to receive either the trial product VIQUA® (250mg in capsules) or Placebo (Dextrin 250mg in capsules) once daily (daily dosage of 300mg) for 36 weeks. Patients were asked to take Viqua or the placebo orally in the morning before breakfast.

Block randomization is used to divide potential patients into m blocks of size 2n, randomize each block such that n patients are allocated to A and n to B then choose the blocks randomly. This method ensures equal treatment allocation within each block if the complete block is used.

The primary outcome measure is the change in bone mineral density (BMD) from baseline to 36 weeks. BMD of the lumbar spine and proximal femur were assessed by dual-energy x-ray absorptiometry at baseline, 12 weeks, 24 weeks, and 36 weeks.

The secondary outcome measures include bone turnover markers, inflammatory status, and antioxidant status of the body. Bone turnover markers tested are osteocalcin, bone-specific alkaline phosphatase (BAP), receptor activator of nuclear factor kappa-B ligand (RANKL), and C-terminal telopeptide. For the analysis of these blood markers, blood samples were collected after 12h overnight fasting and samples were immediately centrifuged and stored for biochemical analysis. All blood markers were tested at baseline, and 12, 24, and 36 weeks.

Intervention Type
Supplement

Primary outcome(s)
Change in bone mineral density (BMD) from baseline to 36 weeks. BMD of the lumbar spine and proximal femur are assessed by dual-energy x-ray absorptiometry at baseline, 12 weeks, 24 weeks, and 36 weeks

Key secondary outcome(s))
The following secondary outcome measures are assessed at baseline, and 12, 24, and 36 weeks:
1. Serum levels of bone turnover markers, osteocalcin, bone-specific alkaline phosphatase (BAP), receptor activator of nuclear factor kappa-B ligand (RANKL), and C-terminal telopeptide measured using biochemical analysis of blood
2. Inflammatory status measured using hs-CRP analysis in blood
3. Antioxidant status measured using Total Antioxidant Status analysis in blood

Completion date
31/07/2023

Eligibility

Key inclusion criteria
1. Post-menopausal female subjects
2. Aged between 45 and 70 years old
3. Subjects with at least 12 months of amenorrhea
4. T-score of −2.5 or less in bone mineral density analysis

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
45 years

Upper age limit
70 years

Sex
Female

Total final enrolment
60

Key exclusion criteria
1. History of cancer or thyroid dysfunction
2. Hormone replacement therapy (HRT) within the last 6 months
3. Known allergy to any of the ingredients in the test product
4. Consumed any nutritional supplements within 1 month from the start of the study
5. Any serious mental or physical illnesses that might interfere with the outcome of the study

Date of first enrolment
02/09/2022

Date of final enrolment
14/10/2022

Locations

Countries of recruitment
Japan

Study participating centre
Medica Tokyo Laboratories
14-5 Kusunokichō, Nishi-ku
Yokohama-shi
Kanagawa-ken
Yokohama
Japan
220-0003

Sponsor information

Organisation
INNOVATION LABO Sciences Co., Ltd

Funder(s)

Funder type
Industry

Funder Name
INNOVATION LABO Sciences Co., Ltd

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Yuki Ikeda, development@innovationlabo.com. Anonymised IPD will be available upon publication of results and for a period of 2 years. Consent from participants was required and obtained.

IPD sharing plan summary
Available on request