

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

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 07/07/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 04/07/2023	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

**EudraCT/CTIS number**  
Nil known

**IRAS number**

**ClinicalTrials.gov number**  
Nil known

**Secondary identifying numbers**  
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

## **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

Home, Hospital, Medical and other records

## **Study type(s)**

Quality of life, Treatment, Efficacy

## **Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet

## **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 measure**

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

### **Secondary outcome measures**

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

### **Overall study start date**

19/07/2021

### **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

### **Age group**

Mixed

### **Lower age limit**

45 Years

### **Upper age limit**

70 Years

### **Sex**

Female

### **Target number of participants**

60

**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**

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**Sponsor information****Organisation**

INNOVATION LABO Sciences Co., Ltd

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**Sponsor type**

Industry

**Website**

<https://www.innovationlabo.com>

## **Funder(s)**

**Funder type**

Industry

**Funder Name**

INNOVATION LABO Sciences Co., Ltd

## **Results and Publications**

**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal

**Intention to publish date**

31/01/2024

**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](mailto: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