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# Moderate consumption of a functional wine enriched in polyphenols on markers of metabolic syndrome, antioxidant profile, and oxidative damage

**Submission date**
20/01/2026

**Recruitment status**
No longer recruiting

**Registration date**
26/01/2026

**Overall study status**
Completed

**Last Edited**
22/01/2026

**Condition category**
Nutritional, Metabolic, Endocrine

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

**Plain English summary of protocol**
Plain English summary of protocol not provided at time of registration.

## Contact information

**Type(s)**
Principal investigator, Scientific, Public

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## Additional identifiers

## Study information

**Scientific Title**
Low-alcohol and low-calorie wines with clinically demonstrated superior antioxidant functionality: development of production strategies and market validation

## Study objectives
To study the effect of moderate consumption of a functional wine enriched in polyphenols, low in alcohol and calories, versus a control wine (low in alcohol, with traditional polyphenol content) through a clinical trial in men and women on markers of metabolic syndrome, antioxidant profile, and oxidative damage.

## Ethics approval required
Ethics approval required

## Ethics approval(s)
approved 12/04/2024, UC Health Sciences Scientific Ethics Committee (Av. Libertador Bernardo O'Higgins 340, Santiago, 8320165, Chile; +56 95504 2397; eticadeinvestigacion@uc.cl), ref: 230502020

## Primary study design
Interventional

## Allocation
Randomized controlled trial

## Masking
Blinded (masking used)

## Control
Dose comparison

## Assignment
Parallel

## Purpose
To study the effect of moderate consumption of a functional wine enriched in polyphenols , low in alcohol and calories, versus a control wine (low in alcohol, with traditional polyphenol content) through a clinical trial in men and women on markers of metabolic syndrome, antioxidant profile, and oxidative damage.

## Study type(s)

## Health condition(s) or problem(s) studied
Consumption of functional wine enriched with wine polyphenols will contribute to restoring, to a greater extent, cardiometabolic markers and plasma antioxidants, and to reducing oxidative damage in those who consume it, compared to consumption of the same wine without the addition of polyphenols (control wine).

## Interventions
Men and woman between 30 and 65 years of age, regular red wine consumer, were selected to participate in a randomized controlled intervention study of the effect of a functional wine enriched in red wine polyphenols and reduced in alcohol, using the same wine with traditional polyphenol content and low alcohol as a control, on markers of metabolic syndrome, antioxidant profile, and oxidative damage.

Prior to the consumption of the experimental and control wines, the study included a three-week washout period from alcohol consumption, a time considered sufficient for the lipid profile of subjects to return to baseline levels.

After the washout period, the participants were called back to the CICUC to begin the experimental or control intervention. The volunteers were randomly assigned using a computer program to one of these two groups, with the participants, healthcare professionals, and laboratory staff blinded. One group received the functional wine (enriched in polyphenols and reduced in alcohol) and the other received the control wine (conventional polyphenol content and reduced in alcohol).

The biological samples obtained from the subjects were labeled with a code corresponding to the study, followed by the assigned number and the sampling time: T0 (initial time) and Tf (final time). Thus, the laboratory personnel who analyzed the respective samples were unaware of a participant's assignment to one intervention or the other.

The participants were instructed to consume 125 ml of wine (1 glass) for women and 250 ml of wine (2 glasses) per day for men, every day with food. The intervention lasted approximately 5-6 weeks (41 days on average), depending on the volunteers' availability to attend the CICUC for the final evaluation and sample collection. In addition, volunteers received a box containing a notebook to record their wine consumption, drinking instructions, a glass marked with a volume corresponding to 125 ml, and a small vacuum pump to properly store the wine in the bottle. The wine was delivered to the volunteers' homes.

During the intervention period, subjects were required to abstain from consuming any wine or alcoholic beverage other than the one provided for the study. Furthermore, participants were not required to change their lifestyle or dietary habits during the study, except for the consumption of the wine, which was the subject of the study.

During the first weeks of the study, each volunteer was monitored by email or telephone weekly, followed by contact every two weeks until the end of the intervention. Participants were able to consult with the nutritionist in charge if they had any concerns.

To reducing oxidative damage in those who consume the functional wine, compared to consumption of the control wine measured using At baseline (T0) and final (Tf), each participant underwent a medical and nutritional interview, where a clinical history and cardiovascular risk factors were completed, focusing on the components of metabolic syndrome. Anthropometric indicators (weight, height, waist circumference, BMI) and blood pressure were measured. In addition, each volunteer's lifestyle was assessed through validated self-report surveys, such as: - Diet using the Mediterranean Diet Index for Chile, an instrument developed and validated by our Center
- Eating and Resting Habits, an instrument developed and validated by our Center
- Physical Activity, using the Spanish version of the Short IPAQ Questionnaire
- Smoking.
Venous Blood Sampling At baseline and final, each participant underwent a fasting venous blood sample collection along with a urine sample collected early in the morning. The following measurements were performed on the collected blood samples:
• UC Christus Health Network Central Laboratory: CBC and HSV, biochemical profile, lipid profile, liver profile, insulin, and creatinine.
• Molecular Nutrition and Chronic Diseases Laboratory:
- Blood antioxidant profile: vitamin C, total antioxidant capacity (TAR).
- Blood markers of oxidative damage: AOPP (oxidative damage in proteins) and oxidized LDL

(oxidative damage in oxidized lipoprotein fatty acids).
– Advanced glycation endpoints (AGEs): total fluorescent AGEs in plasma by stationary fluorescence. Low molecular weight fluorescent AGEs.
- Total polyphenols in urine at Six weeks

### Intervention Type
Supplement

### Primary outcome(s)
1. Blood markers of oxidative damage: Advanced Oxidation Protein Products (AOPPs) in plasma measured using a spectrophotometric assay at at baseline and at the end of the intervention period (6 weeks)

2. Oxidized LDL (oxidative damage in oxidized lipoprotein fatty acids): Oxidized low-density lipoprotein (oxLDL) measured using the oxLDL/MDA Adduct Enzyme-Linked ImmunoSorbent Assay (ELISA) Kit at at baseline and at the end of the intervention period (6 weeks)

3. Blood markers of antioxidant profile: Vitamin C levels in blood samples measured using spectrophotometry using a multi-detection microplate reader to analyse L-Ascorbic acid at at baseline and at the end of the intervention period (6 weeks)

4. Total antioxidant capacity (TAR): The total plasma antioxidant reactivity (TAR) measured using luminol-enhanced chemiluminescence at at baseline and at the end of the intervention period (6 weeks)

### Key secondary outcome(s))
1. Blood markers of low-molecular-weight advanced glycation end products (AGEs) measured using HPLC-FL-DAD and expressed as percentage fluorescence relative to a bovine serum albumin standard at at baseline and at the end of the intervention period (6 weeks)

2. Blood markers of metabolic syndrome and others: Biochemical profile, lipid profile, liver profile, creatinine, insulin in serum measured using a spectrophotometer autoanalyzer with reagent kits purchased from the manufacturer; insulin is measured using electrochemiluminescence immunoassay (ECLIA) at at baseline and at the end of the intervention period (6 weeks)

3. Anthropometric and Blood Pressure Measurements: Height and weight measured using standard methods at at baseline and at the end of the intervention period (6 weeks)

4. Systolic and diastolic blood pressures measured using the left arm at heart level after at least 5 min of resting in a sitting position, using an Automatic upper arm blood pressure monitor HEM-7120 at at baseline and at the end of the intervention period (6 weeks)

5. Mediterranean Diet Score: Overall food intake measured using the self-reported Chilean Mediterranean Diet Index (Chilean-MDI) at at baseline and at the end of the intervention period (6 weeks)

### Completion date
23/12/2024

## Eligibility

## Key inclusion criteria
1. Voluntary acceptance to participate in the study
2. Signed informed consent
3. Male or female between 30 and 65 years of age
4. Regular red wine consumer (≥ 3 times per week)
5. Wine consumption with an AUDIT (Alcohol Use Disorders Identification Test) score of less than 8 points
6. Individuals who are overweight (body mass index (BMI) between 25 and 35 kg/m2) or who present one of the following components of metabolic syndrome:
6.1. Waist circumference > 90 cm in men or > 80 cm in women
6.2. Blood triglycerides ≥ 150 mg/dl
6.3. Blood HDL cholesterol < 40 mg/dl in men or < 50 mg/dl in women
6.4. High blood pressure ≥ 135/80 mmHg
6.5. Fasting blood glucose ≥ 100 mg/dl

Participants who were taking antioxidant supplements and were willing to discontinue use, as well as individuals with pharmacologically controlled hypertension and hypercholesterolemia treated for at least 1 year with lipid-lowering drugs, were accepted into the study.

## Healthy volunteers allowed
No

## Age group
Mixed

## Lower age limit
30 years

## Upper age limit
65 years

## Sex
All

## Total final enrolment
43

## Key exclusion criteria
1. Obesity with a BMI > 35 kg/m2
2. Presence of:- Diabetes mellitus- Severe dyslipidemia (triglycerides > 500 mg/dl and/or total cholesterol > 300 mg/dl)
3. Active liver disease - Rheumatological or other disease that could alter measurements
4. History of any previous clinical cardiovascular event
5. Use of antioxidant supplements or drugs that could alter the lipid profile
6. Use of psychoactive drugs
7. Possible problematic alcohol use screened for by a score equal to or greater than 8 on the AUDIT (Alcohol Use Disorders Identification Test) questionnaire

## Date of first enrolment
12/08/2024

**Date of final enrolment**
14/11/2024

# Locations

**Countries of recruitment**
Chile

**Study participating centre**
**Centro de Nutricion Molecular y Enfermedades Cronicas, Escuela de Medicina, Pontificia Universidad Catolica de Chile**
Santiago
Chile

# Sponsor information

**Organisation**
Pontificia Universidad Católica de Chile

**ROR**
https://ror.org/04teye511

# Funder(s)

**Funder type**

**Funder Name**
Corporación de Fomento de la Producción

**Alternative Name(s)**
Corporation of Promotion of Production, Production Development Corporation, CORFO

**Funding Body Type**
Government organisation

**Funding Body Subtype**
Local government

**Location**
Chile

# Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary
Data sharing statement to be made available at a later date