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Study evaluating the effects of GOZEN BIOMATCHA® on vascular health

Submission date 02/03/2026	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 12/03/2026	**Overall study status** Completed	
Last Edited 12/03/2026	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
Endothelial dysfunction is an early sign of cardiovascular disease. GOZEN BIOMATCHA® is a matcha-based supplement developed to support vascular health. This study evaluates its effect on blood vessel function, nitric oxide levels, inflammation, lipid profile, and oral microbiome composition over 4 weeks.

Who can participate?
Men and women aged 35–55 years with mild cardiovascular risk factors but no diagnosed cardiovascular disease.

What does the study involve?
Participants take either GOZEN BIOMATCHA® or placebo tablets daily for 4 weeks. Vascular tests, blood tests, and oral swabs are collected at baseline and Week 4.

What are the possible benefits and risks of participating?
Participants may experience improvements in vascular function and cardiometabolic markers. Risks are minimal and include possible mild supplement-related adverse events. Safety is monitored via clinical exams and laboratory testing.

Where is the study run from?
Gozen Biotech (Japan)

When is the study starting and how long is it expected to run for?
September 2025 to November 2025

Who is funding the study?
Gozen Biotech (Japan)

Who is the main contact?
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Study information

Scientific Title

A single-center, prospective, randomized, double-blind, two-arm, parallel-group, placebo-controlled clinical trial to evaluate the efficacy of GOZEN BIOMATCHA® on vascular endothelial function (SPG-derived reactive hyperemia), conduit artery dilation (FMD/NMD), nitric oxide metabolites, inflammatory biomarkers, lipid profile, and oral microbiome composition over 4 weeks in middle-aged adults with mild subclinical cardiovascular dysfunction

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 13/05/2025, Swiss Association of Anti-Aging Nutrition (Löwenstrasse 11, Zurich, 8001, Switzerland; +41 (0)7811 47 83; rfaber.saan@gmail.com), ref: 2025/05-THS246

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Mild subclinical cardiovascular dysfunction

Interventions
Participants are randomized in a 1:1 allocation ratio to receive either GOZEN BIOMATCHA® or a matched placebo in a double-blind, parallel-group design. Block randomization are used to allocate participants to each group.

GOZEN BIOMATCHA® is a proprietary matcha-based dietary supplement formulated as oral tablets. Each tablet contains 300 mg of the active formulation. Participants assigned to the active arm consume four tablets daily (total daily dose 1,200 mg) for a duration of 4 weeks. The placebo consists of inert excipients matched in appearance, weight, taste, and packaging to maintain blinding integrity.

The investigational product and placebo are administered orally and taken daily for 4 consecutive weeks. Compliance is assessed through tablet count and subject self-report. All efficacy and safety assessments are conducted at baseline (Week 0) and at the end of the intervention period (Week 4).

Intervention Type
Supplement

Primary outcome(s)
1. Vascular endothelial function measured using strain gauge plethysmography (SPG)-derived reactive hyperemia of the forearm at Screening, Baseline (Week 0), and Week 4

Key secondary outcome(s))
1. Flow-mediated dilation (FMD) measured using high-resolution vascular ultrasound; % change in brachial artery diameter at baseline and week 4

2. Nitroglycerin-mediated dilation (NMD) measured using ultrasound assessment after sublingual nitroglycerin; % change in arterial diameter at baseline and week 4

3. Oral microbiome composition measured using qPCR analysis of oral swab samples at baseline and week 4

4. Endothelial and inflammatory biomarkers measured using hs-CRP using ELISA assay, Syndecan-1 using ELISA assay; NOx using colorimetric reaction assay at baseline and week 4

5. Lipid profile measured using enzymatic colorimetric assay (total cholesterol), enzymatic assay (HDL , LDL, triglycerides) at baseline and week 4

Completion date
20/11/2025

Eligibility

Key inclusion criteria
1. Adults aged 35–55 years
2. Body mass index (BMI) 19.0–30.0 kg/m²
3. Reduced endothelial vasoreactivity (≤5.0 ml/100 ml tissue/min by SPG)
4. Low-density lipoprotein (LDL) >120 mg/dl and/or triglycerides >150 mg/dl
5. No diagnosed cardiovascular disease requiring pharmacological treatment
6. Not using medications affecting vascular function
7. Able to provide written informed consent

Healthy volunteers allowed
Yes

Age group
Adult

Lower age limit
35 years

Upper age limit
55 years

Sex
All

Total final enrolment
60

Key exclusion criteria
1. Diagnosed cardiovascular disease
2. Uncontrolled hypertension (≥160/100 mmHg)
3. Diabetes mellitus
4. Hepatic, renal, or GI disease
5. Active inflammatory or infectious disease
6. Use of lipid-lowering or vascular medications
7. Pregnancy or breastfeeding
8. Substance abuse
9. Recent participation in another clinical trial

Date of first enrolment
10/09/2025

Date of final enrolment
30/09/2025

Locations

Countries of recruitment
Switzerland

Sponsor information

Organisation
Gozen Biotech

Funder(s)

Funder type

Funder Name
Gozen Biotech

Results and Publications

Individual participant data (IPD) sharing plan

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