

# Effects of tea bags containing lyophilized nectarine peaches rich in abscisic acid on blood glucose in individuals with dysglycemia

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<b>Registration date</b> 02/10/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 02/10/2024	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Dysglycemia includes conditions like impaired fasting glucose (IFG) and impaired glucose tolerance (IGT), which are risk factors for developing type 2 diabetes. Thinned nectarines are unripe fruits that are naturally high in abscisic acid (ABA), a plant hormone that has shown potential to improve blood sugar regulation by enhancing glucose uptake in cells. Chromium, specifically in its trivalent form, is a trace mineral that plays a role in insulin sensitivity and glucose metabolism. The combination of these two ingredients is expected to help regulate blood sugar levels in people with dysglycemia, a condition where blood sugar is higher than normal but not yet at diabetic levels.

### Who can participate?

Adult patients aged between 18 and 75 years old with dysglycemia, and a body mass index (BMI) between 20 and 35 kg/m<sup>2</sup>

### What does the study involve?

Participants in the study will be randomly assigned to one of three groups: one group will receive tea bags with thinned nectarines and chromium, another group will receive tea bags with thinned nectarines only, and the third group will receive tea bags containing a placebo. The study will last for 12 weeks, during which participants will consume two cups of infusion per day, one with lunch and one with dinner. Blood samples will be collected at the start and end of the study to measure blood sugar control (HbA1c), cholesterol, and other markers. Additionally, participants will complete a health survey (SF-12) at various time points.

### What are the possible benefits and risks of participating?

The possible benefit of participating in the study is improved blood sugar control, as well as improvements in other metabolic health markers. However, participants may experience no improvement. The ingredients of the infusion are legally approved for use in food supplements, and no adverse effects are expected. Nevertheless, participants will be monitored closely, and any side effects will be reported and addressed.

Where is the study run from?

The medical practice of Dr. Matteo Laringe, located on Via Maria Bakunin, 41, 80126 Naples, Italy.

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

May 2023 to April 2024

Who is funding the study?

NGN Healthcare - New Generation Nutraceuticals s.r.l., the sponsor provides the tea formulations and placebo free of charge.

Who is the main contact?

Dr. Matteo Laringe, [matteo.laringe@gmail.com](mailto:matteo.laringe@gmail.com)

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## **Additional identifiers**

## **Study information**

### **Scientific Title**

Randomized, 3-month, placebo-controlled trial to evaluate the effects of tea bags containing lyophilized nectarine peaches rich in abscisic acid on glycemic control in dysglycemic patients

### **Acronym**

NECTAGLY

### **Study objectives**

Abscisic acid (ABA), a phytohormone known for its role in plant growth and response to environmental stress, has been shown in recent studies to influence glucose homeostasis in humans by stimulating glucose uptake via the activation of GLUT4 receptors. This study hypothesizes that the consumption of tea bags containing lyophilized nectarine peaches, rich in abscisic acid (ABA), with or without trivalent chromium, will significantly improve glycemic control in individuals with dysglycemia when compared to a placebo. The active components in the infusion, particularly ABA and trivalent chromium, are believed to exert beneficial effects on glucose metabolism by enhancing insulin sensitivity and promoting glucose uptake in peripheral tissues.

### **Ethics approval required**

Ethics approval required

### **Ethics approval(s)**

approved 06/06/2023, Ethical Committee "Campania Centro" - Asl Napoli 1 (Via Comunale del Principe 13/a 80145, Naples, 80145, Italy; +390812544550; rpd@aslnapoli1centro.it), ref: n°255 of 06/06/2023

### **Study design**

Three-arm randomized controlled clinical trial

### **Primary study design**

Interventional

### **Study type(s)**

## Efficacy

### **Health condition(s) or problem(s) studied**

Dysglycemia including impaired fasting glucose (fasting blood glucose  $\geq 100$  and  $< 126$  mg/dL) and impaired glucose tolerance (blood glucose levels  $\geq 140$  mg/dL and  $< 200$  mg/dL after 120 minutes of an oral glucose tolerance test).

### **Interventions**

Patients are randomly allocated to three intervention groups:

1. Placebo (PL) group: Participants in the placebo group will consume two placebo infusions per day (one with lunch and one with dinner) for 12 weeks. Each tea-bag contains 2.0 g of microcrystalline cellulose.
2. Thinned nectarines with abscisic acid and chromium (ABA + Cr) group: Participants in this group will consume two infusions per day (one with lunch and one with dinner) for 12 weeks. Each tea-bag contains 2.0 g of lyophilized nectarines and 80 mcg of trivalent chromium.
3. Thinned nectarines with abscisic acid only (ABA) group: Participants in this group will consume two infusions per day (one with lunch and one with dinner) for 12 weeks. Each tea-bag contains 2.0 g of lyophilized nectarines (rich in abscisic acid).

All treatments will be self-administered. Treatment compliance will be assessed by the number of tea-bags returned during specified clinic visits. Throughout the study, patients will be instructed to begin their assigned treatments the day after receiving the intervention. All treatments will be provided free of charge. Periodic and standardized telephone interviews will be conducted by qualified personnel to verify and enhance protocol compliance. Participants will be randomized using sealed envelopes containing randomization numbers. The random number list will be generated by an investigator with no clinical involvement in the trial.

### **Intervention Type**

Supplement

### **Primary outcome(s)**

Serum glycated hemoglobin (HbA1c) level measured using a commercially available kit (InterMedical s.r.l, Italy) in blood samples collected at baseline and after 12 weeks of treatment

### **Key secondary outcome(s)**

The following secondary outcome measures will evaluate several metabolic and health-related markers at baseline and 4, 8, and 12 weeks of treatment:

1. Fasting glucose, total cholesterol, LDL cholesterol, HDL cholesterol, triglycerides, AST (aspartate aminotransferase), and ALT (alanine aminotransferase) measured using commercially available kits (Diacron International, Italy)
2. Fasting insulin levels, measured using an enzyme-linked immunosorbent (ELISA) assay commercial kit (InterMedical s.r.l, Italy)
3. Homeostatic model assessment of insulin resistance (HOMA index), calculated with the formula: fasting glucose (mg/dl) times fasting insulin ( $\mu\text{UI/ml}$ ) divided by 22.5
4. The quality of life of participants measured using the SF-12 health survey questionnaire at baseline and after 4, 8 and 12 weeks of treatment

### **Completion date**

15/04/2024

## **Eligibility**

**Key inclusion criteria**

1. Male and female participants of Caucasian ethnicity, aged between 18 and 75 years
2. Dysglycemia, defined as impaired fasting glucose (fasting blood glucose between 100 and 126 mg/dL) and/or Impaired Glucose Tolerance (blood glucose levels  $\geq 140$  mg/dL and  $< 200$  mg/dL after 120 minutes of an Oral Glucose Tolerance Test)
3. Body mass index (BMI)  $> 20$  and  $< 35$  kg/m<sup>2</sup>
4. Ability to understand and sign the informed consent form

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

18 years

**Upper age limit**

75 years

**Sex**

All

**Total final enrolment**

120

**Key exclusion criteria**

1. HbA1c  $> 6.5\%$
2. Total cholesterol  $> 250$  mg/dL and triglycerides  $> 200$  mg/dL
3. Cardiovascular events (myocardial infarction and/or stroke) in the last 6 months
4. Renal insufficiency (creatinine  $> 1.5$  mg/dL) and hepatic insufficiency (ALT/AST and/or gamma-glutamyl transpeptidase ( $\gamma$ -GT) twice above normal values)
5. Anemia (Hb  $< 12$  g/dL) or other chronic diseases
6. Habitual intense physical activity
7. Gastrointestinal disorders
8. Weight variation  $> 3$  kg in the previous 3 months
9. Malignant neoplasms
10. Significant neurological or psychiatric disorders, including alcohol or drug abuse
11. Patients on therapy with: hypoglycemic agents (both pharmaceutical and nutraceutical), laxatives,  $\beta$ -agonists (except inhalers), cyproheptadine, antidepressants, antiserotonergics, phenothiazines, barbiturates, oral corticosteroids, and antipsychotics
12. Pregnant or breastfeeding women, or women of childbearing age not using adequate contraception

**Date of first enrolment**

04/09/2023

**Date of final enrolment**

29/09/2023

## Locations

**Countries of recruitment**

Italy

**Study participating centre****Comegen-Social Cooperative Society**

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## Sponsor information

**Organisation**

NGN Healthcare—New Generation Nutraceuticals s.r.l.

## Funder(s)

**Funder type**

Industry

**Funder Name**

NGN Healthcare—New Generation Nutraceuticals s.r.l.

## 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 reasonable request from Prof Gian Carlo Tenore, giancarlo.tenore@unina.it.

The data that will be shared include anonymized data related to the primary and secondary outcome measures. The data will be made available upon publication of the study results for a timeless period following publication. The participant information sheet is linked to the present record, together with the study synopsis. All shared data will be fully anonymized to ensure participants' privacy. This will involve removing all personal identifiers in compliance with the General Data Protection Regulation (GDPR). No significant ethical or legal restrictions have been

identified at this time. Data sharing complies with ethical approval received from the Ethical Committee "Campania Centro" (approval number: n°255 of 06/06/2023).

## IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	PIS and informed consent in Italian version 01	19/04/2023	11/09/2024	No	Yes
<a href="#">Protocol file</a>	in Italian version 01	19/04/2023	11/09/2024	No	No