

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

Submission date 10/09/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 02/10/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 02/10/2024	Condition category 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/m²

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

Contact information

Type(s)

Principal investigator

Contact name

Mr Matteo Laringe

Contact details

Via Maria Bakunin, 41

Naples

Italy

80126

+ 39 3939406629

matteo.laringe@gmail.com

Type(s)

Scientific

Contact name

Prof Gian Carlo Tenore

ORCID ID

<https://orcid.org/0000-0002-0251-9936>

Contact details

Via Domenico Montesano, 49

Naples

Italy

80131

+39 81678607

giancarlo.tenore@unina.it

Type(s)

Public

Contact name

Dr Elisabetta Schiano

ORCID ID

<https://orcid.org/0000-0002-8167-0334>

Contact details

Torrette Via Nazionale 207

Mercogliano

Italy

83013

+39 3405387058

elisabettaschiano@gmail.com

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

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 ≥ 100 and < 126 mg/dL) and impaired glucose tolerance (blood glucose levels ≥ 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 (μ 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/m²
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 (γ -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, β -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**

Via Maria Bakunin, 41

Naples

Italy

80126

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?
Participant information sheet	PIS and informed consent in Italian version 01	19/04/2023	11/09/2024	No	Yes
Protocol file	in Italian version 01	19/04/2023	11/09/2024	No	No