ISRCTN90922084 https://doi.org/10.1186/ISRCTN90922084

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

Registration date
02/10/2024

Overall study status
Completed

Last Edited
02/10/2024

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice, Home, Telephone

Study type(s)
Efficacy

Participant information sheet
See study outputs table

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 measure

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

Secondary outcome measures
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 (µUI/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

Overall study start date
15/05/2023

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 ≥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

Age group
Mixed

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
The target number of participants for the clinical trial is 120, with 40 participants per treatment group. This accounts for an estimated 10% dropout rate and a 20% sensitivity to placebo effect

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.

Sponsor details

Torrette Via Nazionale, 207
Mercogliano
Italy
83013
+3405387058
NGNHealthcare@gmail.com

Sponsor type
Industry

Funder(s)

Funder type
Industry

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

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
28/10/2024

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