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The beneficial effect on sugar metabolism of a food supplement based on plant extracts, zinc and chromium

Submission date
24/01/2024

Recruitment status
No longer recruiting

Registration date
16/02/2024

Overall study status
Completed

Last Edited
03/03/2026

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Metabolic Syndrome (MetS) is a multifactorial disease given the diverse range of risk factors involved and the numerous complications that can develop over time, affecting various bodily systems. Lifestyle modifications, especially dietary habits can significantly reduce MetS prevalence. When lifestyle changes and a healthy diet are insufficient to manage risk factors associated with MetS, medications become essential for controlling blood pressure, improving insulin sensitivity, and reducing cholesterol and triglyceride levels. In cases where lifestyle modifications are ineffective but before resorting to medication, the use of food supplements could be a safe and effective strategy for mitigating MetS risk factors. In recent years, researchers have been looking into a new extract from a type of Italian purple corn (Zea mays L.) known as Moradyn. This extract, rich in polyphenols, shows promise in inhibiting digestive enzymes that break down carbohydrates and preventing the formation of AGEs (advanced glycation end-products) – substances associated with aging. Additionally, leaves from the Gymnema sylvestre plant have been studied for their potential to control blood sugar levels. These leaves contain various beneficial compounds, including gymnemic acid, guaranine peptide, stigmasterol, quercetol, betaine, choline, and trimethylamine. There is also a connection between mineral deficiency, particularly in zinc and chromium, and disruptions in glucose and insulin regulation. Zinc is crucial for insulin synthesis and secretion, as well as for pathways that regulate insulin's actions. A zinc deficiency is linked to risk factors for diabetes and cardiovascular diseases. Chromium, another essential element, acts as a cofactor for insulin. Inadequate chromium intake may lead to increased insulin secretion, resulting in issues like hyperinsulinemia, insulin resistance, and weight gain. This clinical trial aims to demonstrate that the food supplement consisting of Zea mays L. and Gymenema sylvestre (Retz.) R.br. ex Sm extracts, zinc, and chromium play a positive role in maintaining the normal metabolism of carbohydrates and lipids, bringing benefits to the subjects who take this food supplement.

Who can participate?
Patients aged 18-77 years old who present impaired fasting blood glucose

What does the study involve?
Participants will consume a food supplement based on Moradyn® (purple corn variety extract Zea mays L. fruit), Gymnema sylvestre (Retz.) R.Br. ex Sm. leaves, zinc and chromium, at two different doses, or a placebo, for 90 days, based on the randomization group.

What are the possible benefits and risks of participating?
An improvement in the clinical cardiovascular health of participants in the two food supplement groups is hypothesized. However, no benefit may be achieved. No risks are foreseen.

Where is the study run from?
National Inter-university Consortium of Research in Innovative Pharmaceutical Technologies - Tefarco Innova (Italy)

When is the study starting and how long is it expected to run for?
February 2021 to December 2021

Who is funding the study?
National Inter-university Consortium of Research in Innovative Pharmaceutical Technologies - Tefarco Innova (Italy)

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
GLIKUR_01

Study information

Scientific Title
Efficacy study of the food supplement based on Moradyn® (purple corn variety extract Zea mays L.), Gymnema, Zinc, and Chromium, commercial name “GLIKUR Advance” for the maintenance of normal carbohydrate metabolism through the reduction of slightly altered plasma glucose levels, as cardiovascular risk factors: single-center, controlled, randomized, parallel-group, double-blind clinical study.

Acronym
GLIKUR

Study objectives
This study aims to evaluate the efficacy of the supplementation of the diet with a food supplement based on Moradyn® (purple corn variety extract Zea mays L. fruit), Gymnema sylvestre (Retz.) R.Br. ex Sm. leaves, zinc and chromium, in the maintenance of normal carbohydrate metabolism through the reduction of plasma glucose levels in patients with impaired fasting plasma glucose (fasting plasma glucose between 90 and 120 mg/dL), which numerous clinical studies define as an important cardiovascular risk factor.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 18/04/2021, Ethics Committee of North Campania (Contrada Amoretta - Città Ospedaliera, Avellino, 83100, Italy; +39 (0)825/203025; comitatoeticoav@gmail.com), ref: 817

Study design
Interventional monocentric randomized parallel three-arm double-blind placebo-controlled clinical trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Impaired fasting plasma glucose (fasting plasma glucose between 90 and 120 mg/dL)

Interventions
The subjects recruited in the present clinical study will consume a food supplement based on Moradyn® (purple corn variety extract Zea mays L. fruit), Gymnema sylvestre (Retz.) R.Br. ex Sm. leaves, zinc and chromium, at two doses (1560 mg/day – 2 tabs, or 780 mg/day - 1 tab), or a placebo, for 90 days, based on the randomization group.
In particular, to maintain the double-blind design, Group 1 will be treated with two tablets of Glikur Advance (based on Moradyn®, Gymnema, Zinc and Chromium) daily for 3-months, Group 2 will be treated with one tablet of the dietary supplement and one tablet of cellulose (placebo) daily for 3-months, while Group 3 consisted of subjects who have taken two tablets of placebo, according to the parallel group design.
The randomization sequence will be generated by a statistician using STATA 16 software (Stata Statistical Software: Release 16. College Station, TX: StataCorp LLC) and the randomization list will be kept hidden. The participants will be assigned to each of the two treatment groups (food supplement or placebo) casually and by simple randomization (1:1:1 allocation ratio). The randomization code will consist of a three-digit number as indicated in the respective Case Report Form (CRF).

In the clinical study, 81 participants will be enrolled and divided into three groups (27 for each group):

- Group 1: two tablets of the dietary supplement Glikur Advance* (based on Moradyn®, Gymnema, Zinc and Chromium) daily for 3-months
- Group 2: one tablet of the dietary supplement Glikur Advance* and one tablet of cellulose (placebo) daily for 3-months
- Group 3: two tablets of placebo daily for 3-months

Participants will undergo three visits (baseline = t0; after 30 days of treatment = t1; after 90 days of treatment = t2) in an outpatient setting. After each clinical visit, all data are filled in the CRF by physicians.
The clinical trial design is reported below:
During the screening visit, subjects will undergo the study participation requirements

confirmation:
- Impaired fasting glycemia (IFG) between 98 and 125 mg/dl.

Subsequently, all enrolled subjects will undergo the following:
- at t0, and t2 (at baseline, and 90 days from the start of treatment) the recruited subjects were submitted to blood sampling for the evaluation of the following biochemical parameters: fasting glucose levels, HbA1c, insulin, HOMA Index, total cholesterol (TC), Low-Density Lipoproteins (LDL-C) cholesterol, High-Density Lipoprotein (HDL-C) cholesterol, Triglycerides (TG), SGOT and SGPT (hepatic toxicity), Creatinine (renal toxicity).

Intervention Type
Supplement

Primary outcome(s)
Improvement in fasting plasma glucose levels measured using blood tests for fasting serum glucose levels, HbA1c, fasting serum insulin levels and HOMA Index at baseline (t0), 90 days of treatment (t2)

Key secondary outcome(s))
1. Beneficial effect on lipid metabolism measured using the determination of blood levels of total cholesterol (TC), Low-Density Lipoproteins (LDL-C) cholesterol, High-Density Lipoprotein (HDL-C) cholesterol, Triglycerides (TG) at baseline (t0), 90 days of treatment (t2)
2. Height/weight assessment to calculate BMI at baseline (t0), 90 days of treatment (t2)
3. Liver and kidney toxicity measured using blood tests for the biomarkers aspartate transaminase (AST or SGOT), alanine transaminase (ALT or SGPT), and creatinine at baseline (t0), 30 days of treatment (t1), 90 days of treatment (t2).

Completion date
13/12/2021

Eligibility

Key inclusion criteria
1. Aged 18-75 years old of both sexes
2. Able to understand and sign the informed consent
3. 98 mg/dL < impaired fasting glycemia < 125 mg/dL

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
81

Key exclusion criteria
1. Aged < 18 and > 75 years old
2. A medical history or condition that could affect the subject's safety or negatively impact the validity of the study results
3. Pregnant or breastfeeding women
4. With a history of allergy to ingredients contained in the study treatments (dietary supplement and placebo)
5. Exposed to a high risk of cardiovascular events based on 8 risk factors (sex, age, diabetes, smoking habits, systolic blood pressure, total cholesterolemia, hdl-cholesterolemia and antihypertensive treatment)
6. Following drug therapy for diabetes even at low dosages
7. Taking supplements to control cholesterol, blood sugar and metabolic syndrome, in the two weeks prior to recruitment
8. Women who suspect pregnant or planning pregnancy
9. Blood donors in the three months prior to recruitment
10. Non-self-sufficient individuals
11. Who does not show a propensity to collaborate
12. Who have difficulty getting to the reference facility within the scheduled time
13. Who are not considered suitable by the investigators due to the presence of other pathologies considered incompatible with enrollment.

Date of first enrolment
13/05/2021

Date of final enrolment
10/06/2021

Locations

Countries of recruitment
Italy

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Sponsor information

Organisation
National Inter-university Consortium of Research in Innovative Pharmaceutical Technologies - Tefarco Innova

Funder(s)

Funder type
Research organisation

Funder Name
National Inter-university Consortium of Research in Innovative Pharmaceutical Technologies - Tefarco Innova

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the subsequent results publication.

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		28/07/2024	03/03/2026	Yes	No