ISRCTN15020073 https://doi.org/10.1186/ISRCTN15020073

Exploring the benefits of grape pomace supplements for diabetic eye health: new clinical trial results

Submission date
04/07/2024

Recruitment status
No longer recruiting

Registration date
08/07/2024

Overall study status
Completed

Last Edited
05/08/2025

Condition category
Eye Diseases

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

Plain English summary of protocol

Background and study aims
Diabetic retinopathy (DR) is a common complication of diabetes that can lead to vision loss if not properly managed. This study explores the potential benefits of a nutraceutical supplement made from grape pomace, a byproduct of winemaking, in improving eye health for people with DR. Grape pomace contains natural compounds known for their antioxidant and anti-inflammatory properties. In this study, patients with DR are randomly assigned to receive either the grape pomace supplement or a placebo (an inactive substance) for six months. The main goals are to see if the supplement can reduce swelling in the retina (the light-sensitive tissue at the back of the eye) and improve vision. Additionally, the study looks at whether the supplement can d reduce oxidative stress, which is a harmful process linked to many diabetic complications. Participants undergo thorough eye exams and blood tests at the beginning and end of the study to measure these effects. By comparing the results between the supplement and placebo groups, researchers aim to determine if the grape pomace supplement offers a new, effective way to support eye health and manage diabetic retinopathy. This research could lead to new strategies for preventing vision loss in people with diabetes.

Who can participate?
The patient has been diagnosed with mild to moderate non-proliferative diabetic retinopathy (a type of eye damage caused by diabetes) according to standard guidelines. They are receiving eye treatment through injections directly into the eye, which help to reduce the harmful effects of a protein that can cause vision problems. This patient is over 18 years old, and an eye scan has shown a small area of swelling in the retina that is less than 400 micrometers thick.

What does the study involve?
The study involves the administration of a nutraceutical supplement made from maltodextrinated grape pomace extract (MaGPE) to patients diagnosed with mild and moderate non-proliferative diabetic retinopathy (DR). Participants will be randomly assigned to receive either the MaGPE supplement or a placebo for six months. The main objectives are to assess whether the supplement can reduce central retinal thickness (CRT) and improve best-corrected visual acuity (BCVA). Additionally, the study will examine the impact of the supplement on

oxidative stress markers. Participants will undergo comprehensive eye examinations, including optical coherence tomography (OCT) and visual acuity tests, at the beginning and end of the study. Blood tests will also be conducted to measure oxidative stress and other relevant biomarkers. Participants will be required to maintain their usual diet and lifestyle throughout the study and to record their supplement intake and any side effects in daily monitoring tables.

What are the possible benefits and risks of participating?
Participants in the study may experience several potential benefits, including a reduction in retinal swelling, improved visual acuity, and overall better eye health. The MaGPE supplement, derived from grape pomace, is rich in polyphenolic compounds known for their antioxidative and anti-inflammatory properties. These properties may help in mitigating retinal damage and enhancing vascular integrity, thereby slowing the progression of diabetic retinopathy and improving overall visual outcomes. Potential risks may include side effects from the MaGPE supplement, such as gastrointestinal discomfort or allergic reactions. The placebo group might not receive the same potential benefits as the group receiving the MaGPE supplement. Participants will be closely monitored throughout the study, and any adverse effects will be managed by the research team to ensure participant safety.

Where is the study run from?
Inventia Biotech-Healthcare Food Research Center s.r.l. (Italy)

When is the study starting and how long is it expected to run for?
September 2020 to September 2021

Who is funding the study?
Inventia Biotech-Healthcare Food Research Center s.r.l. (Italy)

Who is the main contact?
vscorcia@unicz.it
elisabettaschiano@inventiabiotech.com

Contact information

Type(s)
Public, Principal investigator

Contact name
Prof Vincenzo Scorcia

ORCID ID
https://orcid.org/0000-0001-6826-7957

Contact details
Department of Ophthalmology, University Magna Græcia of Catanzaro
Catanzaro
Italy
88100
+39 961721986
vscorcia@unicz.it

Type(s)

Scientific

Contact name
Dr Elisabetta Schiano

ORCID ID
https://orcid.org/0000-0002-8167-0334

Contact details
Inventia Biotech-Healthcare Food Research Center s.r.l., Strada Statale Sannitica KM 20.700
Caserta
Italy
81020
+39 3405387058
elisabettaschiano@inventiabiotech.com

Additional identifiers

Protocol serial number
N° 311 of 17/09/20

Study information

Scientific Title
Efficacy of a nutraceutical formulation based on maltodextrinated grape pomace extract in patients with diabetic retinopathy: a randomized, single-blind, placebo-controlled trial

Acronym
DRIPE

Study objectives
This study hypothesizes that the nutraceutical formulation based on maltodextrinated grape pomace extract (MaGPE) has a beneficial impact on patients with diabetic retinopathy (DR). Specifically, it is expected that MaGPE supplementation leads to significant reductions in central retinal thickness (CRT) and improvements in best-corrected visual acuity (BCVA) compared to placebo. Additionally, MaGPE is anticipated to decrease oxidative stress markers. The underlying premise is that the polyphenolic compounds in grape pomace, known for their antioxidative and anti-inflammatory properties, will mitigate retinal damage and enhance vascular integrity, thereby slowing the progression of DR and improving overall visual outcomes.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 17/09/2020, Calabria Region Ethics Committee, Central Area Section (Via Tommaso Campanella, 115, Catanzaro, 88056, Italy; +39 961883550; cometico@aocz.it), ref: N 311

Study design
Monocentric interventional double-blind parallel-group randomized controlled trial

Primary study design
Interventional

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Improvement of ophthalmic outcomes in patients with diabetic retinopathy

Interventions
The intervention in this study consists of administering a nutraceutical formulation based on maltodextrinated grape pomace extract (MaGPE) to patients with diabetic retinopathy (DR). The MaGPE supplement is derived from Aglianico cultivar grapes and is produced through a patented process that includes extraction with water at 50°C, followed by filtration, concentration, and spray-drying with maltodextrins to obtain a fine microencapsulated powder. Each tablet contains 400 mg of MaGPE. Participants in the MaGPE group are instructed to take two gastro-resistant tablets of MaGPE twice daily, resulting in a total daily intake of 800 mg of MaGPE. The placebo group receives an identical regimen of tablets containing maltodextrins, which serve as the control intervention. The placebo tablets are designed to match the appearance and taste of the MaGPE tablets to maintain blinding.
Both groups are advised to maintain their usual diet and lifestyle throughout the study period. Participants are also required to record their supplement intake and any side effects in daily monitoring tables. Compliance with the intervention is monitored through periodic follow-up visits and tablet counts.

Participants were randomised by drawing of envelopes containing randomisation numbers. The random number list was generated by an investigator with no clinical involvement in the trial.

Intervention Type
Supplement

Primary outcome(s)
1. Central Retinal Thickness (CRT) measured using optical coherence tomography (OCT), at baseline (T0) and six-months (T6)
2. Best-Corrected Visual Acuity (BCVA) assessed using the 4 m logarithmic visual acuity chart with an Early Treatment Diabetic Retinopathy System (ETDRS) chart, at baseline (T0) and six-months (T6)

Key secondary outcome(s))
Measured at baseline (T0) and after six months of treatment (T6):
1. Glucometabolic Parameters:
1.1. Fasting Plasma Glucose (FPG) measured using commercially available kits (Diacron International, Italy). Blood samples are collected from participants after an overnight fast
1.2. Fasting Plasma Insulin (FPI): FPI levels are determined using an enzyme-linked immunosorbent assay (ELISA)
1.3. The Homeostatic Model Assessment of Insulin Resistance (HOMA-IR) is calculated using the formula: FPG (mg/dL) × FPI (μU/mL) / 405.
1.4. Total cholesterol (TC), low-density lipoprotein cholesterol (LDL-C), high-density lipoprotein cholesterol (HDL-C), and triglycerides (TG) are measured using commercial enzymatic kits
2. Oxidative Stress Markers:
2.1. Reactive Oxygen Metabolites (d-ROMs): The levels of d-ROMs are measured using an

automated analyzer (Free Carpe Diem, Diacron International, Grosseto, Italy) with commercially available kits (Diacron International)
2.2. Oxidized Low-Density Lipoprotein (oxLDL): oxLDL levels are assessed using an automated analyzer (Free Carpe Diem, Diacron International, Grosseto, Italy) with commercially available kits (Diacron International)

Completion date
13/09/2021

Eligibility

Key inclusion criteria
1. Confirmed diagnosis of mild and moderate non-proliferative diabetic retinopathy (DR) based on the International Clinical Diabetic Retinopathy (ICDR) and Diabetic Macular Edema Severity Scale
2. Ocular treatment with intravitreal anti-VEGF injections
3. Age over 18 years
4. Focal edema identified by OCT scan measuring less than 400 µm

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
80 years

Sex
All

Total final enrolment
99

Key exclusion criteria
1. Presence of other retinal diseases linked with macular edema
2. Active or suspected ocular or periocular infection, active epithelial keratitis (dendritic keratitis), mycobacterial and fungal infections, advanced glaucoma, aphakic eye with rupture of the posterior capsule, eyes with anterior chamber intraocular lenses, scleral-fixated and iris-fixated intraocular lens and with rupture of the posterior capsule, recent ocular surgery (within the last 3 months), and ischemic maculopathy
3. Severe hepatic, renal, and cardiovascular diseases, other chronic degenerative diseases such as cancer, pregnancy, suspicion of pregnancy, breastfeeding, birch pollen allergy, and the use of medications or supplements containing grape polyphenols.

Date of first enrolment
11/01/2021

Date of final enrolment
08/03/2021

Locations

Countries of recruitment
Italy

Study participating centre
Department of Ophthalmology, University Magna Græcia
Viale Europa
Catanzaro
Italy
88100

Sponsor information

Organisation
Inventia Biotech-Healthcare Food Research Center s.r.l.

Funder(s)

Funder type
Industry

Funder Name
Inventia Biotech-Healthcare Food Research Center s.r.l.

Results and Publications

Individual participant data (IPD) sharing plan
Data of individual patients will be available upon request of patient permission
vscorcia@unicz.it; elisabettaschiano@inventiabiotech.com

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		26/08/2024	05/08/2025	Yes	No