ISRCTN13100451 https://doi.org/10.1186/ISRCTN13100451

New low-salt foods seasoned with grape extracts: sensory evaluation and functional assessment in the prevention of hypertension and control of glycaemia

Submission date
01/11/2020

Recruitment status
No longer recruiting

Registration date
27/11/2020

Overall study status
Completed

Last Edited
13/01/2022

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Current plain English summary as of 05/11/2021:
Background and study aims
Several studies have reported the health benefits of grape pomace (GP) supplementation since it is a dietary source of polyphenols and fiber. GP is a good candidate for a clinical trial of the management of both blood pressure and glucose levels. Moreover, grape pomace has promising sensory potential as a condiment in food but this property is still not scientifically proven. This trial is included in a R+D+i Project (INGRAPE) funded by the Spanish Ministry of Science and Innovation, the aim of which is to assess the use of GP seasoning as a salt replacer in foods to reduce markers of high blood pressure and high blood sugar in people at risk and in healthy people.

Who can participate?
Both patients and healthy subjects. Patients with at least two of the following risk factors: high blood pressure, high blood cholesterol, high blood fats, increased fasting blood sugar, and increased waist size. Healthy subjects with normal values in these parameters.

What does the study involve?
Participants will undergo 6 weeks of reducing salt in their food (control group) or supplementation with 2 g/day of grape pomace seasoning as a salt replacer (treatment group). Participants provide samples of faeces, saliva and blood for analysis at the start and the end of the study.

What are the possible benefits and risks of participating?
The researchers expect the GP seasoning to reduce blood pressure and blood sugar levels and cause changes in gut bacteria. Therefore, the participants in the intervention group will benefit from these potential health effects. In a general way, all participants will get satisfaction from

contributing to a study that could lead to an interesting strategy to manage high blood pressure and blood sugar. As far as the researchers are aware, participating does not lead to additional risks.

Where is the study run from?
CIAL-Institute of Food Science Research, Spanish National Council (CSIC) (Spain)

When is the study starting and how long is it expected to run for?
December 2016 to November 2019

Who is funding the study?
Spanish Ministry of Science and Innovation (Spain)

Who is the main contact?
1. Diego Taladrid
d.taladrid@csic.es
2. Begoña Bartolomé
b.bartolome@csic.es
3. Dr M. Victoria Moreno Arribas
victoria.moreno@csic.es

Previous plain English summary:
Background and study aims
Several studies have reported the health benefits of grape pomace (GP) supplementation since it is a dietary source of polyphenols and fiber. GP is a good candidate for a clinical trial of the management of both blood pressure and glucose levels. Moreover, grape pomace has promising sensory potential as a condiment in food but this property is still not scientifically proven. This trial is included in a R+D+i Project (INGRAPE) funded by the Spanish Ministry of Science and Innovation, the aim of which is to assess the use of GP seasoning as a salt replacer in foods to reduce markers of high blood pressure and high blood sugar in people at risk.

Who can participate?
Participants with at least two of the following risk factors: high blood pressure (systolic ≥130 mmHg or diastolic >85 mmHg), high blood cholesterol (HDL cholesterol <40 mg/dl in men and <50 mg/dl in women), high blood fats (triglycerides >150 mg/dl), increased fasting blood sugar (>100 mg/dl), increased waist size (> 94 cm in men and > 80 cm in women)

What does the study involve?
Participants will undergo 6 weeks of reducing salt in their food (control group) or supplementation with 2 g/day of grape pomace seasoning as a salt replacer (treatment group). Participants provide samples of faeces, saliva and blood for analysis at the start and the end of the study.

What are the possible benefits and risks of participating?
The researchers expect the GP seasoning to reduce blood pressure and blood sugar levels and cause changes in gut bacteria. Therefore, the participants in the intervention group will benefit from these potential health effects. In a general way, all participants will get satisfaction from contributing to a study that could lead to an interesting strategy to manage high blood pressure and blood sugar. As far as the researchers are aware, participating does not lead to additional risks.

Where is the study run from?
CIAL-Institute of Food Science Research, Spanish National Council (CSIC) (Spain)

When is the study starting and how long is it expected to run for?
December 2016 to November 2019

Who is funding the study?
Spanish Ministry of Science and Innovation (Spain)

Who is the main contact?
1. Diego Taladrid
d.taladrid@csic.es
2. Begoña Bartolomé
b.bartolome@csic.es
3. Dr M. Victoria Moreno Arribas
victoria.moreno@csic.es

Contact information

Type(s)
Scientific

Contact name
Dr M. Victoria Moreno Arribas

ORCID ID
https://orcid.org/0000-0002-4136-595X

Contact details
c/Nicolás Cabrera, 9
Madrid
Spain
28049
+34 (0)910017900
victoria.moreno@csic.es

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
RTC-2016-4556-1

Study information

Scientific Title
Hypertension- and glycaemia-lowering effects of a grape-pomace-derived seasoning in patients and healthy volunteers. Interplay with the gut microbiome

Acronym
INGRAPE

Study objectives
Grape pomace has demonstrated before its functional properties in the management of risk factors of metabolic syndrome. Moreover, grape pomace has an underestimated culinary potential.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/05/2017, The Spanish National Research Council Ethics Committee (117 Serrano Street, Madrid, 28006, Spain; +34 (0)915681494; subcomitedebioetica@csic.es), ref: RTC-2016-4556-1

Study design
Interventional controlled randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Not avaliable in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Management of metabolic risk factors of metabolic syndrome

Interventions
First, volunteers will receive information about the study, a survey of dietary habits and several recipes low in sodium salt. In addition, they will have to sign a printed consent to participate in the study, donate their biological samples and to ensure confidentially of the data.

Then, participants will be allocated randomly to the control and treatment groups. All of them will go through a washout period in which they will have to reduce their intake of polyphenol-rich foods for 2 weeks. After that, both sets of volunteers will have to reduce the consumption

of sodium salt during the 6 weeks of the clinical trial. Furthermore, the treatment group will have to consume 2 g/day of grape pomace as sodium salt replacer in their foods.

The first day after the washout period and the last day of the intervention period, all of the participants will go to the collection place between 8:00-10:00 after at least 10 hours of fasting. Then, they will deliver a sample of faeces taken as recent to this moment as possible (in a stool collection tube introduced in an anaerobic plastic zip bag). Then they will have to spit into a 15 ml Falcon tube to obtain at least 3 ml of saliva.

After the delivery of the samples, anthropometric data of height, weight and waist circumference will be taken. In addition, blood pressure will be measured during relaxation in triplicate using a digital oscillometric device (Omron model M6 Comfort, Omron Corporation, Tokyo, Japan) and employing at least two readings.

By last, participants will be allocated one by one to a contiguous room where a sample of blood will be taken by a specialist belonging to an independent laboratory, who is also responsible for the blood analysis.

Intervention Type
Supplement

Primary outcome measure
1. Full serum count, erythrocyte sedimentation rate, c-reactive protein, sodium, potassium, chloride, bicarbonate, urea, creatinine, bilirubin, gamma-glutamyl transferase, total protein, albumin, calcium, phosphate, uric acid, random blood glucose, cholesterol, high-density lipoprotein, low-density lipoprotein and triglycerides; measured using a blood test at baseline and at the end of the control/intervention period
2. Blood pressure (mmHg), height (cm), weight (kg), waist diameter (cm) and hip circumference (cm) measured at baseline and at the end of the control/intervention period

Secondary outcome measures
1. Short-chain fatty acids (SCFA) and phenolic metabolites analysed in faecal samples by gas chromatography–mass spectrometry (GC-MS) and ultra-high performance liquid chromatography mass spectrometry (UHPLC–MS), respectively, according to previous laboratory procedures at baseline and at the end of the control/intervention period
2. Microbiota sequencing analysis of faecal samples following a bacteria metagenomic approach (Illumina technology) at baseline and at the end of the control/intervention period

Overall study start date
10/12/2016

Completion date
21/11/2019

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 05/11/2021:
Patients:
Presenting with at least two of the following risk factors of metabolic syndrome:
1. Hypertension (systolic BP ≥130 mmHg or diastolic BP >85 mmHg)

2. Hypercholesterolemia (HDL colesterol <40 mg/dl in men and <50 mg/dl in women)
3. Hypertriglyceridemia (triglycerides >150 mg/dl)
4. Increased fasting plasma glucose (>100 mg/dl)
5. Increased waist circumference (>94 cm in men and >80 cm in women)

Healthy participants:
Presenting with normal values of the parameters mentioned above.

Previous participant inclusion criteria:
Participants have to present at least two of the following risk factors of metabolic syndrome:
1. Hypertension (systolic BP ≥130 mmHg or diastolic BP >85 mmHg)
2. Hypercholesterolemia (HDL colesterol <40 mg/dl in men and <50 mg/dl in women)
3. Hypertriglyceridemia (triglycerides >150 mg/dl)
4. Increased fasting plasma glucose (>100 mg/dl)
5. Increased waist circumference (>94 cm in men and >80 cm in women)

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
30

Total final enrolment
31

Key exclusion criteria
1. Serious cardiovascular disease
2. Antibiotic intake up to 3 months before the study
3. Endocrine and gastrointestinal disorders
4. Addiction to drugs or alcohol
5. Restrictive diets (vegetarians, vegans)

Date of first enrolment
01/06/2017

Date of final enrolment
10/09/2018

Locations

Countries of recruitment
Spain

Study participating centre
Instituto de Investigación en Ciencias de la Alimentación
Nicolás Cabrera street, 9
Madrid
Spain
28049

Sponsor information

Organisation
Institute of Food Science Research

Sponsor details
c/ Nicolas Cabrera, 9
Madrid
Spain
28049
+34 (0)910017900
victoria.moreno@csic.es

Sponsor type
Research organisation

Website
http://www.cial.uam-csic.es/en/

ROR
https://ror.org/04dgb8y52

Funder(s)

Funder type
Government

Funder Name
Ministerio de Asuntos Económicos y Transformación Digital

Results and Publications

Publication and dissemination plan
1. Planned publication in a high-impact journal
2. Participants desiring to know the outcomes of the study will be informed individually by email

3. The protocol and the statistical analysis will be available when the results are published in a scientific journal

Intention to publish date
20/12/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study (serum blood analytics, anthropometrical data, blood pressure, faecal metabolites and sequencing data) are/will be available upon request from Diego Taladrid (d.taladrid@csic.es), Begoña Bartolomé (b.bartolome@csic.es), and M.Victoria Moreno-Arribas (victoria.moreno@csic.es). Data were anonymized but participants desiring to know the outcomes of the study were informed individually of their corresponding data by email.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		12/01/2022	13/01/2022	Yes	No