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Intake of chayote extract (sechium edule) for treatment of metabolic syndrome in older adults

Submission date
03/06/2018

Recruitment status
No longer recruiting

Registration date
21/06/2018

Overall study status
Completed

Last Edited
14/07/2023

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
The metabolic syndrome (MetS) is a set of alterations in the metabolism of sugar and fats, which causes an increase in the concentration of sugar (glucose) and blood fats (cholesterol and triglycerides), because insulin does not work adequately (insulin resistance). Patients with MetS also have obesity, high blood pressure and predisposition to form blood clots that can obstruct the circulation of the arteries and cause irreversible damage to the heart tissue (myocardial infarction) or brain tissue (cerebral infarction) . Likewise, it has been shown that MetS increases some chemical molecules that damage cells called free radicals that if not counteracted with antioxidants, a biochemical imbalance called oxidative stress is presented, in addition to a chronic inflammatory process, both alterations damage cells and tissues, which causes many chronic diseases. The frequency of MetS in young adults (20-29 years) is less than 10%; however, in individuals ≥ 60 years of age, the frequency increases to more than 40%. MetS in older adults is a risk factor for type 2 diabetes mellitus, cardiovascular diseases, cognitive impairment and frailty. For this reason, different therapeutic alternatives have been proposed. In this sense, it has been reported that the leaves and fruits of chayote (Sechium edule) have an anti-inflammatory, antioxidant effect and regulate the proper use of fats by the body (lipogenesis). Therefore, it has been reported that the consumption of chayote extract decreases blood concentration of fats and sugar (triglycerides, cholesterol and glucose), so they have been used in the treatment of high blood pressure. However, there are no studies on the effect of chayote consumption on oxidative stress and chronic inflammation in older adults with MetS.
For this reason, this study aims to evaluate the effects of chayote consumption on oxidative stress, chronic inflammation in older adults with metabolic syndrome.

Who can participate?
Adults aged 60 to 74 years with metabolic syndrome

What does the study involve?
Participants are randomly allocated to one of three groups.
Those in the first group take two capsules containing chayote extract (Sechium edule) every day for 12 months.

Those in the second group take two capsules containing a placebo (dummy drug) every day for 12 months.
Those in the third group do not have any treatment.
At the beginning of the study and after three, six and 12 months, blood pressure, height, and waist and hip circumference are taken and blood samples are taken to evaluate.

What are the possible benefits and risks of participating?
Participants who intake chayote extract (Sechium edule) can improve their biochemical and clinical alterations (high blood glucose and cholesterol concentration, and insulin resistance) as well as oxidative stress (decreased free radicals, increased antioxidant enzymes and decreased DNA damage), and chronic inflammation.
Participants in the supplementation groups may experience gastrointestinal symptoms, nausea, diarrhea, loss of appetite and abdominal discomfort.
There are no direct risks in the placebo and without treatment groups.

Where is the study run from?
National Autonomous University of Mexico (Mexico)

When is the study starting and how long is it expected to run for?
March 2017 to June 2020

Who is funding the study?
1. General Directorate of Academic Personnel Affairs, National Autonomous University of Mexico (Mexico)
2. Secretariat of Science, Technology and Innovation of Mexico City (Mexico)

Who is the main contact?
Dr Victor Manuel Mendoza-Núñez (Scientific)
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Study website
https://www.zaragoza.unam.mx/unidad-de-investigacion-en-gerontologia/

Contact information

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PAPIIT IN218718 and SECITI/045/2018

Study information

Scientific Title
Effect of intake of sechium edule (chayote) extract on oxidative stress, chronic inflammation and DNA damage in older adults with metabolic syndrome

Study objectives
According to scientific evidence about antioxidant, anti-inflammatory and hypoglycemic effect of sechium edule (chayote), older adults with metabolic syndrome (MetS) who intake this compound will show improvement on glycemic control, lipidic profile, oxidative stress and chronic inflammation and will avoid complications due to MetS.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Bioethics and Research Committee of Facultad de Estudios Superiores Zaragoza UNAM, 29/05 /2017, ref: 23/02 / SO / 2.4.2

Study design
Interventional non-randomised study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Metabolic syndrome

Interventions
Participants are randomly allocated to one of three groups. Those in the first group are asked to take two capsules that contain 500 mg of Sechium edule extract every day for 12 months. Those in the second group are asked to take two capsules that contain a placebo (dummy drug) every day for 12 months; and the third group go without treatment. At the beginning of the study and after three, six and 12 months, the blood pressure (systolic and diastolic) and anthropometric measures are taken (height, waist circumference and hip) and blood samples are taken to evaluate: glucose, cholesterol, triglycerides, oxidative stress, chronic inflammation, and DNA damage.

Intervention Type
Supplement

Primary outcome measure
1. Markers of oxidative stress in blood: isopeotans measured by ELISA, antioxidant enzymes superoxide dismutase (SOD) and glutathione peroxidase (GPx), and total antioxidant activity evaluated through the spectrophotometry technique at baseline at 3, 6 and 12 months
2. Markers of chronic inflammation in blood are measured by flow cytometry: TNF-α, IL-1β, IL-6, IL-8, IL-1, IL-12p70, at baseline, 3, 6 and 12 months
3. Oxidative damage to DNA is measured through the comet assay technique at the beginning, 3, 6 and 12 months

Secondary outcome measures
1. Blood glucose concentration, triglycerides, cholesterol and HDL are measured by spectrometry, and glycosylated hemoglobin is measured by turbidimetry, at baseline 3, 6 and 12 months
2. Systolic and diastolic blood pressure is measured with a mercury sphygmomanometer, at baseline, 3, 6 and 12 months
3. Weight, body mass index, waist and hip circumference are measured at baseline, 3, 6 and 12 months

Overall study start date
01/03/2017

Completion date
30/06/2020

Eligibility

Key inclusion criteria
1. Age from 60 to 74 years old
2. Diagnosed with metabolic syndrome
3. Have taken antioxidant and / or anti-inflammatory supplements in the last 6 months
4. Signature of informed consent

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
One hundred and twenty participants will be randomly allocated to one of three groups (40 subjects each one). Those in the first group are asked to take two capsules that contain 500 mg of Sechium edule extract every day for 12 months. Those in the second group are asked to take two capsules that contain a placebo (dummy drug) every day for 12 months; and the third group without treatment. At the beginning of the study and after three, six and 12 months, the blood pressure (systolic and diastolic), anthropometric measures will be taken (height, waist circumference and hip) and blood samples will be taken to evaluate: glucose, cholesterol, triglycerides, oxidative stress, chronic inflammation, and DNA damage.

Key exclusion criteria
1. Without kidney damage
2. Without liver damage
3. Without cancer

Date of first enrolment
21/06/2018

Date of final enrolment
29/06/2020

Locations

Countries of recruitment
Mexico

Study participating centre
Research Unit in Gerontology, FES Zaragoza, National Autonomous University of Mexico
Guelatao # 66 Colonia Ejército de Oriente Delegación Iztapalapa
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Sponsor information

Organisation

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Sponsor type
University/education

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ROR
https://ror.org/0079gpv38

Funder(s)

Funder type
Not defined

Funder Name
General Directorate of Academic Personnel Affairs, National Autonomous University of Mexico (DGAPA, UNAM) and Secretariat of Science, Technology and Innovation of Mexico City (SECITI)

Results and Publications

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

Intention to publish date
30/06/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request in writing from Unidad de Investigación en Gerontología, Facultad de Estudios Superiores Zaragoza, UNAM.

Additional documentation:
The study protocol may also be requested in writing from Unidad de Investigación en Gerontología, Facultad de Estudios Superiores Zaragoza, UNAM.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Antioxidant and Anti-Inflammatory Effect of the Consumption of Powdered Concentrate of Sechium edule var. nigrum spinosum in Mexican Older Adults with Metabolic Syndrome	28/05/2022	14/07/2023	Yes	No
Results article	Effect of Sechium edule var. nigrum spinosum (Chayote) on Oxidative Stress and Pro-Inflammatory Markers in Older Adults with Metabolic Syndrome: An Exploratory Study	27/05/2019	14/07/2023	Yes	No
Results article	Effect of Sechium edule var. nigrum spinosum (Chayote) on Telomerase Levels and Antioxidant Capacity in Older Adults with Metabolic Syndrome	18/07/2020	14/07/2023	Yes	No