

Effect of Pistachio (*Pistacia Vera* L.) Consumption on Locomotor Activity and Molecular Regulation of the Circadian Clock in Adipose Tissue of Overweight Adults

September 2021

Annex IV. Informed Consent Intervention Study

Folio: 1111

of person evaluated.

M = male

F = female

Treatment M = 1

P = 2 and FM = 3

Date of application: Folio: 1111

Interviewer:

Evaluation period:

2019-1/PROPAC-ProyPis-Cron

Initials (Subject's name):

AUTONOMOUS UNIVERSITY OF QUERÉTARO

Graduate Program in Food Science, Faculty of Chemistry

“Consent Form to Participate in a Research Project”

Protocol Title

“Effect of pistachio (*Pistacia vera* L.) consumption on locomotor activity and molecular regulation of the circadian clock in adipose tissue of overweight adults”

Principal Investigator: Dr. Rocio Campos Vega

Study site: Graduate Program in Food Science, Faculty of Chemistry, Autonomous University of Querétaro

INVITATION

You are being invited to participate in this research study. Before deciding whether to participate, you must know and understand each of the following sections. This process

is known as informed consent. Feel completely free to ask about any aspect that may help clarify your doubts.

Once you have understood the study and if you wish to participate, you will be asked to sign this consent form, of which you will receive a signed and dated copy.

1. STUDY JUSTIFICATION

Pistachio (*Pistacia vera* L.) is a food associated with various health benefits, attributed to its high content of phenolic compounds and phyto-melatonin. Melatonin functions as a regulator of our biological clock, with beneficial effects on sleep cycle regulation. Melatonin is naturally present in pistachios but can also be consumed as a supplement in safe doses (up to 5 mg).

Sleep is a regular periodic phenomenon that adapts to biological time variations (day/night) through biological rhythms known as circadian cycles. The circadian rhythm is described as a cycle close to 24 hours, allowing recognition of sleep-wake phenomena and their balance in biological processes of all living beings.

“Chronodisruption (CD)” refers to the alteration of this 24-hour cycle, manifested in physiological, biochemical, and behavioral changes. Current evidence suggests that chronodisruption is associated with increased risk of developing diseases such as obesity. Therefore, this study will evaluate the effect of pistachio consumption as a snack on improving chronodisruption and, consequently, metabolic processes associated with obesity, as well as elucidating the mechanism by which this effect occurs.

2. STUDY OBJECTIVE

To evaluate the effect of pistachio (*Pistacia vera* L.) consumption on plasma melatonin, antioxidant capacity, and circadian rhythms in overweight young adults.

3. STUDY BENEFITS

This study will provide scientific evidence supporting the biological clock-regulating action of compounds present in pistachios, such as phyto-melatonin, their impact on circadian rhythm regulation, and improvement of metabolic processes altered during obesity.

As a benefit of participation, you will receive your nutritional and medical evaluation results at the beginning of the study. At the end, you will receive results regarding your health status and possible improvements from pistachio consumption, including biochemical results (baseline and final). All studies and assigned treatments will be free of charge.

4. STUDY PROCEDURES

If you agree to participate, you will follow this procedure:

- Duration: 4 weeks.
- Initial assessments: blood samples, stool sample collection, health/sleep/diet questionnaires, and anthropometric measurements (weight, height, waist and hip circumference).
- Intervention: daily portion of pistachios (32 g) at midday.
- Final assessments: fasting blood sample (8-12 h), stool sample, and repeat questionnaires.

Blood samples will be taken twice (baseline and final). Parameters measured: cholesterol, triglycerides, LDL/HDL lipoproteins, insulin, glucose, melatonin, antioxidant capacity, and leukocyte gene expression related to circadian rhythm. Stool samples will be analyzed for short-chain fatty acids and other metabolites.

5. STUDY RISKS

Pistachio consumption poses no risk unless you have a known allergy or intolerance. Pistachios are safe for human consumption.

Blood sampling is routine and poses no health risk, though temporary discomfort or bruising may occur.

6. CLARIFICATIONS

- Participation is voluntary.
 - You may withdraw at any time without consequences.
 - No costs or payments are involved.
 - Confidentiality will be strictly maintained; data will be coded to protect identity.
 - Updated information may be requested during the study.
 - In case of adverse effects, appropriate medical care will be provided.
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7. CONTACT INFORMATION

For questions about participation, consult your physician.

For project-related questions or emergencies, call **442 3432168**, Dr. Rocio Campos Vega.

8. INFORMED CONSENT

I, _____, have read and understood the above information and my questions have been satisfactorily answered. I have been informed and understand that data obtained in the study may be published or disseminated for scientific purposes. I agree to participate in this research study. I will receive a signed and dated copy of this consent form.

Participant's signature

Date

Witness 1 Date

Witness 2 Date

I have explained to Mr./Ms. _____ the nature and purposes of the research; I have explained the risks and benefits of participation. I have answered questions to the best of my ability and asked if there were any doubts. I accept that I have read and know the regulations for conducting research with human subjects and adhere to them.

Investigator's signature Date

9. CONSENT REVOCATION LETTER

Protocol Title:

Principal Investigator:

Study Site:

Participant's Name: _____

Through this letter, I inform my decision to withdraw from this research protocol for the following reasons (Optional):

Participant's name

Participant's or guardian's signature

Date