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Evaluation of energy expenditure at rest and preference for sweet taste during the menstrual cycle (Gasto energético en reposo y preferencia por el sabor dulce durante el ciclo menstrual)

Submission date
13/10/2017

Recruitment status
No longer recruiting

Registration date
31/10/2017

Overall study status
Completed

Last Edited
24/01/2019

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Obesity is increasing worldwide and it affects women in greater proportion. The menstrual cycle is regulated by hormones that influence food intake and energy expenditure. The purpose of this study is to determine the amount of energy that body spends, eating habits and sweet taste preference, in relation to the hormones concentration during the menstrual cycle. This is important to better understand how energy metabolism is regulated in the body and eventually contribute to the prevention and / or treatment of excess weight, particularly in women. This study consists in two sessions during the menstrual cycle of a group of healthy women. The aim of this study is to examine variations in energy expenditure at rest that may be influenced by hormonal variations during the menstrual cycle.

Who can participate?
Healthy women aged 18 to 40 who present regular menstrual cycles without the use of contraceptives.

What does the study involve?
Participants are given a questionnaire and are asked to complete the following screening tests: pregnancy test, past and current medical history, and routine blood testing and to have a registry of the menstrual cycles. Participants are randomly allocated to one of two groups, to know which of the session will be first, corresponding to the menstrual phase. The study includes two sessions. Participants have to come at 8:00 in the morning to start the assessments. The sessions are performed with 15-20 days of interval. In each session procedures are performed: The amount of energy that the body spends (metabolic rate) is measured by determining the amount of breath, by installing a plastic capsule over your head for 20 minutes.

And 1 blood samples of 15 ml in total equivalent to 1 tablespoon is taken. Later, is applied a test for determining sweet taste preferences and complete a consumer frequency survey for the consumption of sweet processed foods and also a question about cravings.

What are the possible benefits and risks of participating?
There are no immediate direct benefit to those taking part. However, the information that will be obtained will be useful to know more about the regulation of energy metabolism and could eventually benefit overweight and obese women. The information of the exams practiced will be given to the participants. There are a few risks with associated with blood samples, participants can feel pain when the needle penetrates the skin, as well as they can feel dizzy or fatigued. There is a risk of hematoma, bleeding and infection at the puncture site. The use of sterile techniques and trained personnel will minimize the risks of infection, hematoma and pain. There are also risks during the measurement of oxygen consumption as participants may feel a sense of claustrophobia given the installation of the clear plastic capsule on your head.

Where is the study run from?
Pontificia Universidad Católica de Chile (Chile)

When is the study starting and how long is it expected to run for?
May 2017 to August 2017

Who is funding the study?
Pontificia Universidad Católica de Chile (Chile)

Who is the main contact?
Dr Jose Galgani Fuentes
jgalgani@uc.cl

Contact information

Type(s)
Scientific

Contact name
Dr Jose Galgani Fuentes

ORCID ID
https://orcid.org/0000-0001-9793-8561

Contact details
Pontificia Universidad Católica de Chile (Santiago)
Departamento de Nutrición, Diabetes y Metabolismo
Alameda 340, interior, 2° patio, 4° Piso
Santiago
Chile
8320000
+56 2 354 6389
jgalgani@uc.cl

Additional identifiers

Protocol serial number
170504007

Study information

Scientific Title
Resting metabolic rate and sweet taste preferences during the menstrual cycle

Acronym
CICLO

Study objectives
During the luteal phase there is a higher energy expenditure at rest and sweet taste preference compared to the follicular phase.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Board at Pontificia Universidad Católica de Chile, 08/06/2017, ref: 170504007

Study design
Single center randomised crossover study

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Resting metabolic rate and sweet taste preferences during the menstrual cycle in healthy women

Interventions
The selected participants are randomly assigned to the first session corresponding to the follicular phase or to the luteal phase. Each participant completes two sessions, performed on one day of each phase of the menstrual cycle. The first day of menstrual bleeding is counted as day one of the cycle and representative ranks of days were established for both phases.

Tests are started the morning after a night fast of 8 to 12 hours. Weight and body composition are measured. Subsequently, the participant is kept at rest for 30 minutes, the vital signs (axillary temperature, blood pressure and pulse) are measured, and once the indicated time is reached (30 min), energy expenditure is measured by indirect calorimetry. Subsequently an indirect calorimetry correction procedure is performed and a blood sample (15 ml) is taken for further analysis (glucose, insulin, estradiol and progesterone). Finally, a standardized test for determining sweet taste preferences is done (Monell Forced-Choiced, Paired-Comparison Tracking Procedure). A consumer frequency survey is applied for the consumption of processed foods with sweet taste and also a question about cravings.

Intervention Type

Other

Primary outcome(s)
1. Resting Metabolic Rate and Respiratory Quotient is measured using indirect calorimetry for 30 minutes, gas exchange is determined by using a metabolic car (Vmax Encore 29n)
2. Estradiol and Progesterone concentration is measured using blood samples when the measurement of resting metabolic rate finishes
3. Sweet taste preference is measured using the Monell Forced-Choiced, Paired-Comparison Tracking Procedure when the other measurement are finished, at minute 45

Key secondary outcome(s))
1. Consumption of processed foods is measured using a consumer frequency survey at the end of the sweet taste preference procedure at one hour after the start of the session
2. Body mass and body composition is measured using the body mass index formula (BMI) (body mass divided by the square of the body height) and the body composition was measured by electrical bioimpedance at the beginning of the session

*All measurements are made in the two sessions, corresponding to each menstrual phase. The day 1 for the menstrual cycle is the first day of bleeding, the range of days for the follicular phase (5-12), and for the luteal (21-27).

Completion date
28/08/2017

Eligibility

Key inclusion criteria
1. Healthy women (by physical examination, past and current medical history, and routine blood testing, including biochemical profile, thyroid-stimulating hormone, free thyroxine, electrolytes, creatinine, and hemogram)
2. Between 18 and 40 years old
3. Stable body weight (change <2,5 kg over the past 3 months)
4. IMC: 18.5 – 30 kg/m2
5. Physical activity (<7 hours/wk)
6. Do not take medications
7. Do not use hormonal contraceptives
8. Non smokers
9. Non pregnant
10. Regular menstrual cycles

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

18 years

Sex
Female

Key exclusion criteria
1. Women with any disease
2. Younger than 18 years old and older than 40 years old.
3. Unstable weight (change>2 kg over the past 3 months),
4. Physical activity (>7 hours/wk)
5. Taking medications or hormonal contraceptives
6. Pregnant women
7. Irregular menstrual cycles
8. Smokers

Date of first enrolment
08/06/2017

Date of final enrolment
21/07/2017

Locations

Countries of recruitment
Chile

Study participating centre
Pontificia Universidad Católica de Chile. Departamento de Nutrición, Diabetes y Metabolismo
Avda. Libertador Bernardo OHiggins 340.
Santiago
Chile
8320000

Sponsor information

Organisation
Fondecyt

Organisation
Departamento de Nutrición, Diabetes y Metabolismo

Organisation
Comisión Nacional de Investigación Científica y Tecnológica

ROR
https://ror.org/02ap3w078

Funder(s)

Funder type
University/education

Funder Name
Pontificia Universidad Católica de Chile (Santiago)

Funder Name
Departamento de Nutrición, Diabetes y Metabolismo

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from: Lorena Malo- Investigator at loremalovinti@gmail.com.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		12/09/2018	12/09/2018	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes