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Microstructure of starch-based meals and change in blood sugar

Submission date	Recruitment status	[_] Prospectively registered
05/04/2019	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/04/2019	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
02/12/2019	Other	

Plain English summary of protocol

Background and study aims
The postprandial glycemic response (response after consuming food) consists of the elevation of blood sugar (glucose) levels that occur after the ingestion of carbohydrate-rich foods. It has been shown that there is great variability in the postprandial response in response to the intake of different foods. Starch is the most abundant source of carbohydrates of vegetable origin. The main objective of the study was to evaluate if the physical properties of solid foods based on starch, gluten and lipids are associated with different postprandial glycemia/insulin responses in response to the intake of starchy foods (starch test and glucose test oral).

Who can participate?
Healthy female volunteers of normal weight, the participants were selected from previous studies.

What does the study involve?
Visit the centre on four occasions one week apart after 8-12 hours of fasting (only water allowed). During the first visit, basic measurements are performed including a blood test. During the second visit, participants have multiple blood tests after eating a small amount. During the third and fourth visit, further meal tests were performed

What are the possible benefits and risks of participating?
Benefits: Participants will not benefit from participating in this biomedical research.However, they may know what their current nutritional status is and their blood sugar and lipid tests. They were given a written document containing general nutritional recommendations and prevention of diabetes mellitus, made by a nutrition professional. If the results of the oral glucose tolerance test were altered, they were given medical advice in this regard
Risks: The extraction of blood can cause pain, bruising, bruising and rarely infection at the puncture site. In the procedures involving several blood samples, only one puncture was performed, obtaining the samples from the same route. To avoid this type of discomfort to the maximum the person who extracted the blood sample had great experience in the procedure

Where is the study run from?
UC Centre of Clinical Research, Santiago, Chile

When is the study starting and how long is it expected to run for?
March 2015 to December 2016

Who is funding the study?
Fondo Nacional de Desarrollo Científico y Tecnológico, Chile.
Supported by a FONDECYT grant (1170594) for J. Parada, and a FONDECYT grant (1150416) for J.L. Santos.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Microstructure of starch-based meals with either palm or soybean oils alter in vitro starch digestibility with no major effects on glycemic responses

Study objectives
Study the effects of the oil type in a solid ternary matrix (starch-oil-protein) on starch digestibility. Additionally, we studied the postprandial glycemic responses to starch-based meals enriched with either palm or soybean oil in volunteers in a pilot study.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/10/2014, Ethics Committee of the School of Medicine of the Pontificia Universidad Católica de Chile (Marcoleta 391, Piso 1, 8330024, Santiago, Chile; 02-2354.8173; etica.investigacion@med.puc.cl), ref: 14-479

Study design
Non-randomised crossover trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
not available in web format, please use contact details to request a participant information cheet

Health condition(s) or problem(s) studied
Healthy volunteers

Interventions
Participants visited the UC Centre of Clinical Research in four occasions one week apart after 8-12 hours of fasting (only water was allowed). During the first visit, basal biochemical and anthropometric measurements were performed. At this stage, subjects with diabetes, glucose intolerance, dyslipidemia or in pregnancy were excluded from the study. During the second visit, participants were submitted to a standard 75g Oral Glucose Tolerance Test (OGTT). Blood samples were drawn at -15, -5, 15, 30, 60, 90 and 120 minutes after glucose ingestion. During the third and fourth visit, meal tests were performed with model solid meals based on starch, wheat gluten and two types of triglycerides based on either palm or soybean oil, which have notable differences in the fraction of palmitic and linoleic acids. The meal consisted of 140 g of a dough containing 25 g of potato starch, 5 g of wheat gluten and 5.7 g of oils (either palm or soybean oil). Each meal was consumed together with 150 mL of tap-water over, at most, five minutes by chewing approximately 15 times before swallowing.

Intervention Type
Other

Primary outcome measure
Plasma glucose, insulin levels and c-peptide, measured by blood sample analysis at -15, -5, 15, 30, 60, 90, and 120 minutes after glucose ingestion and meal test.

Secondary outcome measures
1. Glycemic response after meal tests measured by drawing of blood samples at times -15, -5, 15, 30, 60, 90, and 120 minutes after meal test, for the determination of plasma glucose and insulin levels.
2. Anthropometric and biochemical characteristics measured after 8-12 hours of fasting:
2.1 Age (years)
2.2 Weight (kg)
2.3 Height (m)
2.4 BMI (kg/m^2)
2.5 Fasting Glucose (mg/dl)
2.6 Fasting Insulin (µIU/ml)
2.7 Total cholesterol (mg/dL)
2.8 HDL cholesterol (mg/dL)
2.9 Triglycerides (mg/dL)
2.10 Systolic arterial pressure (mmHg)
2.11 Diastolic blood pressure (mmHg)
The anthropometric measurements were made by personnel trained in light clothing and without shoes, using a calibrated set of stadiometers, scales and tapes. The weight and height were used to calculate the BMI (Kg / m2). Fasting blood samples were taken in the volunteers, and blood glucose, insulinemia, total cholesterol, HDL cholesterol and triglycerides were measured by the laboratory of the Department of Nutrition, Diabetes and Metabolism of the Pontificia Universidad Catolica de Chile

Overall study start date
15/07/2013

Completion date
30/12/2016

Eligibility

Key inclusion criteria
1. Female
2. Normoglycemic
3. Normal weight Body Mass Index of 22 ± 1.9 kg/m2 (Mean ± SD)

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Female

Target number of participants

8

Total final enrolment
8

Key exclusion criteria
1. Family history of diabetes
2. Diabetes
3. Glucose intolerance
4. Dyslipidemia
5. Pregnant

Date of first enrolment
05/03/2015

Date of final enrolment
30/08/2015

Locations

Countries of recruitment
Chile

Study participating centre
UC Centre of Clinical Research
Portugal 61
Santiago
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Sponsor information

Organisation
Pontificia Universidad Católica de Chile

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Sponsor type
University/education

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ROR
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Funder(s)

Funder type
Government

Funder Name
Fondo Nacional de Desarrollo Científico y Tecnológico

Alternative Name(s)
National Fund for Scientific and Technological Development, El Fondo Nacional de Desarrollo Científico y Tecnológico, FONDECYT

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Chile

Results and Publications

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

Intention to publish date
15/06/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
	results				

Results article	20/11/2019	02/12/2019	Yes	No