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Assessment of how quickly a top-quality pasta affects blood sugar (glucose) level when compared to a standard commercial one

Submission date
10/12/2020

Recruitment status
No longer recruiting

Registration date
28/12/2020

Overall study status
Completed

Last Edited
04/01/2021

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Pasta is one of the first sources of carbohydrates in western diet. Dry pasta is a virtually non-perishable food if properly preserved, and it is easy to produce, deliver and store. Moreover, pasta is tasty and easy to cook even for people with low cooking abilities. For these reasons pasta is considered a primary food, and its consumption should be part of a balanced and healthy diet. Nevertheless, pasta is a complex food, made from a whole vegetable grain and processed so that the composition of the vegetable cells is completely lost during the production process. The resulting composition of the flour first and of the dough afterwards can alter the microscopic structure. This may lead to different types of digestion of the carbohydrates that result in a different distribution of the sugars in the bloodstream (glycaemic index). Pasta composition may produce a different glycaemic index.
Carbohydrates play a role in the development and control of some metabolic conditions (e.g. diabetes). Glycaemic index and insulin levels after eating a meal represent key factors in the management of those conditions.
The aim of this study, thus, is to compare the glycaemic index and the insulin production response to the assumption of a pasta produced according to a standard commercial production process with a high-engineered pasta produced with high-tech machines t, aimed to preserve the molecular and microscopic structure of the flour and of the dough. Furthermore, the study aims to evaluate the metabolic response to different types of pasta produced with the same hi-tech solutions, namely the one based on an egg white dough, and one made from semolina dough.
The studio hypothesis is that preserving the fine structure and composition of the wheat and the amides throughout the whole pasta production process, is possible to achieve better glycaemic control and better assimilation and distribution of the sugars to the tissue. In addition, the inclusion of egg white in the dough can also contribute to providing better assimilation and distributions of macronutrients in the bloodstream and therefore in the tissues. This can contribute to producing high-quality pasta that can be used as part of a diet and of treatment in specific metabolic conditions.

Who can participate?
Participants will be enrolled among healthy adult volunteers, with no known diagnosis of metabolic diseases, with a regular diet. The subjects enrolled in the study will be overweight, with a body mass index between 26 and 30 kg/m² and a sedentary lifestyle.

What does the study involve?
Participants will be randomly allocated to receive a meal made with a different pasta each Monday for 4 weeks. Before and after eating blood samples will be taken to test the blood sugar and other constituents of the blood that will inform about how the food is being digested.

What are the possible benefits and risks of participating?
The participants will receive valuable information on their health status and dietetic advice aimed to generally improve their health. No risks.

Where is the study run from?
The study will take place in a primary care setting based in the town of Catanzaro (Italy)

When is the study starting and how long is it expected to run for?
September 2020 to February 2020

Who is funding the study?
The study is funded by Italiana Pastifici s.r.l. (Italy)

Who is the main contact?
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Contact information

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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IP-001

Study information

Scientific Title
A top-quality pasta produced with high-tech engineered procedures lead to better glycaemic control when compared to a standard commercial pasta

Study objectives
The glycaemic index and the glycaemic load of a top-quality high-tech engineered egg-white pasta and a similar pasta of durum wheat semolina is better than the one of a commercial pasta made with traditional technologies resulting in a smoother postprandial glycaemic curve

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/09/2020, Regione Calabria Comitato Etico Sezione Area Centro [Calabria Region Central Area Section Ethics Committee] (Via Tommaso Campanella 115, 88100 Catanzaro, Italy; +39 (0)961712550; comitatoeticocentro@libero.it), ref: 271

Study design
Longitudinal single blind randomized trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Prevention

Participant information sheet
See additional files for participant information in Italian

Health condition(s) or problem(s) studied
Glycaemic index testing of different pastas

Interventions
The subjects enrolled in the study are prescribed a standard healthy diet (defined “AHA type 1 diet” as per the study handbook that will be made available to the investigators before the recruitment phase) throughout the study period. Enrolled subjects will be randomly assigned to a series of 4 sessions according to a Latin square scheme with possible combination considered among the following:
- Standard Oral Glucose tolerance test (OGTT)
- Pietro Massi Egg-White Pasta (PM-EWP)
- Pietro Massi Semolina Pasta (PM-SP)
- Standard Commercial Semolina Pasta (SCP)

Sessions will be one week apart, on a given day (e.g. every Monday for 4 weeks in a row). The test will take place in the morning at the same time.
The subject is requested to come to the test after a fasting period of 10 hours. Only 200 ml of water is admitted, although drinks are not allowed for the 30 minutes before the start of the test.
On the day of the test the subject assumes a 1 g/Kg of Body Weight of the food chosen for the day or 70 grams of oral glucose as per a standard OGTT (the standard glucose OGTT is not a comparator, but it is needed for the classification of the subject enrolled in the study, and it can be used during data analysis for subgroup classification)
Cooking time and procedures are standard for every subject and for every type of pasta and strictly follow the producer recommendations. Pasta is cooked in salty boiling water (10 grams of salt per 1 litre of water every 100 grams of pasta); the cooking time is the one suggested by the manufacture (+-20 sec) in all the tests. The pasta will then be taken in the most typical format of the Mediterranean diet, dressed with extra-virgin olive oil (20ml) and 18-22 months mature parmesan cheese (10 grams) and mashed drained peeled tomato (40 grams). The seasonings (for quantity, quality and cooking methods) will be the same for all tests and for all types of pasta (SCP, PM-EWP, PM-SP).
A protracted glucose tolerance test is performed with blood sample taken at baseline, 30 minutes, 60 minutes, 90 minutes, 120 minutes, 180 minutes, 240 minutes. Each sample is tested for blood sugar and insulin levels. The samples are taken from an antecubital vein of the arm after cannulation with an ad hoc catheter. The times are calculated, in the case of the intake of pasta, from the middle of the intake (the catheter is placed in the vein before the start of the intake of the pasta).
The standard indications of the OGTT Guidelines are followed. In particular, the subject for the whole duration of the study does not perform physical exercises or efforts and does not take other foods. Water is allowed in modest quantities (100 ml during the meal and 50 ml after 120 minutes).
The procedure remains the same for all subsequent tests.

Intervention Type
Other

Primary outcome measure
1. Glycaemic index measured using protracted OGTT at baseline, 30 minutes, 60 minutes, 90 minutes, 120 minutes, 180 minutes, 240 minutes
2. Glucose tolerance measured using standard OGTT at pre-baseline
3. Insulin levels measured using blood sample at at baseline, 30 minutes, 60 minutes, 90 minutes, 120 minutes, 180 minutes, 240 minutes

Secondary outcome measures
On the day of the first test and the day of the last test a blood sample is tested for baseline values of the following biomarkers:
1. Total cholesterol
2. LDLc
3. HDLc
4. TG
5. Hb glycated
6. got
7. gpt
8. uricemia

Overall study start date
17/09/2020

Completion date
28/02/2021

Eligibility

Key inclusion criteria
1. Healthy adult volunteer
2. BMI between 26 and 30 kg/m²
3. Sedentary lifestyle
4. Non-smoker

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
20

Key exclusion criteria

1. Known diagnosis of chronic degenerative diseases
2. Known diagnosis of diabetes
3. Known diagnosis of endocrine disease
4. Previous bulimia/anorexia, patients with recent (within 3 months) strong drop or weight increase, weight fluctuations greater than the sum of the analytical and pre-analytical variability physiological according to gender, age and weight, or weight trend on multiple measures constantly increasing or decreasing
5. Food intolerances and subject to food restrictions.

Date of first enrolment
01/12/2020

Date of final enrolment
31/01/2021

Locations

Countries of recruitment
Italy

Study participating centre
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Sponsor information

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Sponsor type
Other

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Funder(s)

Funder type
Industry

Funder Name
Italiana Pastifici s.r.l.

Results and Publications

Publication and dissemination plan
The results will be published on relevant international medical journals.

Intention to publish date
01/03/2022

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		21/12/2020	04/01/2021	No	Yes
Protocol file		21/12/2020	04/01/2021	No	No