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Effect of a bean extract on glucose metabolism in obesity

Submission date	Recruitment status	[ ] Prospectively registered
07/04/2021	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/05/2021	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
20/05/2021	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Among the treatment options for obesity, diet plays a central role. Some foods derived from plants have shown activity in controlling blood glucose after a meal. These compounds are contained in some food supplements such as those based on extracts from common beans. It is demonstrated that this extract reduces the absorption of sugar, leading to an improved blood glucose level in normal weight and overweight people. The aim of this study is to evaluate the medium- to long-term effects of the administration of bean extracts on the capability of insulin to carry out its action in a group of people with severe obesity, compared with a group with similar characteristics treated with a placebo (dummy). The study also aims to evaluate the effects of the extract on food intake.

Who can participate?
People aged between 18 and 65 with a Body Mass Index greater than or equal to 35 kg/m² with altered blood sugar but without type 1 or type 2 diabetes

What does the study involve?
Participants will be randomly allocated into two groups. One group will be given a 100 mg dose of P.V. extract 15-30 minutes before lunch and dinner (total daily dose 200 mg) for a period of 12 weeks, while the control group will be given a placebo (dummy). Both groups follow a balanced low-calorie diet: 50% carbohydrates, 20% protein and 30% fat. Each participant will undergo a nutritional assessment and are assigned a low-calorie diet calculated according to his /her energy requirements (with comparable energy reduction for all participants). Participants will also be asked to perform moderate aerobic physical activity.

What are the possible benefits and risks of participating?
The use of bean extract could help people to control blood sugar levels and, in the long term, lead to improved weight loss. To date, no undesirable effects have been observed; chronic use may lead to digestive symptoms such as bloating or flatulence. These effects will be monitored during the study.

Where does the study run from?
Istituto Auxologico Italiano (Italy)

When is the study starting and how long is it expected to run for?
December 2020 to October 2022

Who is funding the study?
1. Regione Lombardia (Italy)
2. Istituto Auxologico Italiano (Italy)
3. Indena (Italy)

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
2021_01_26_10

Study information

Scientific Title
In vivo effects of chronic administration of a Phaseolus vulgaris extract, containing alpha-amylase inhibitor and agglutinin, on glucometabolic status and the hunger-satiety circuit in subjects with severe obesity

Acronym
MFHBB

Study objectives
Derangements of glucose metabolism, in particular pre-diabetic conditions, are among the most common comorbidities of severe obesity. The use of plant extracts such as Phaseolus vulgaris (P. V.), containing a glycoprotein able to inhibit pancreatic alpha-amylase and thus decrease intestinal absorption of complex carbohydrates, may be effective in these clinical conditions. In addition, Phaseolus extract contains agglutinins which have been shown to modulate the hunger-satiety circuit. The researchers hypothesize that supplementation with a standardized extract of P.V. could improve and modulate the glucometabolic profile compared to diet treatment alone in subjects suffering from severe obesity

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/01/2021, Ethics Committee Istituto Auxologico Italiano IRCCS (Via Ariosto 13, 20145, Milan, Italy; +39 (0)02619112237; comitato.etico@auxologico.it), ref: 2021_01_26_10

Study design
Interventional randomized placebo-controlled double-blind trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Glycometabolic control in patients with severe obesity

Interventions
Randomization:
Block randomisation at https://www.sealedenvelope.com/.

The population will be divided into two arms: to avoid any kind of bias the two arms will be comparable by age, gender and initial weight. One group will be given a 100 mg dose of P.V.

extract 15-30 minutes before lunch and dinner for a period of 12 weeks, while the control group will be given a placebo identical in terms of excipient content with the exclusion of the active ingredient.

Statistical analysis plan:
Data will be reported as mean and standard deviation (SD) for continuous and normally distributed variables (median and interquartile range for non-normally distributed variables) and as absolute and relative frequency for categorical variables. The data from the experiment will be analysed using a repeated-measures ANOVA model by including the period effect, the treatment effect and the interaction between the two in the model. The variance-covariance matrix considered will be of the compound-symmetry type with a constant correlation between times. A sensitivity analysis will be conducted to assess the robustness of the results to changes in the structure of the variance-covariance matrix.

Sample size:
A sample size of 208 subjects, 104 for each arm in the study, will reach a power of 80% in detecting a statistically significant difference of 0.7 between the start and end of treatment in the experimental group and between the start and end of treatment in the placebo group assuming a significance level of 5%. This sample size was calculated by considering a standard deviation of 2 of the differences between the start and end of treatment between the two groups.

Intervention Type
Supplement

Primary outcome(s)
1. Insulin resistance measured using the HOMA Index before and after P.V. extract or placebo treatment at baseline (T0), after 2 weeks (T1), 4 weeks (T2) and after 12 weeks (T6)
2. Serum concentrations of glycated haemoglobin, glucose and insulin measured from blood samples taken before P.V. extract or placebo intake, baseline (T0), after 2 weeks (T1), 4 weeks (T2) and 12 weeks (T6) from the start of treatment

Key secondary outcome(s))
The following outcomes are measured before and after the P.V. extract or placebo treatment at specific time points: before P.V. extract/placebo intake (T0) and after 2 weeks (T1), 4 weeks (T2), 8 weeks (T4) and 12 weeks (T6):
1. Weight and waist circumference measured to the nearest 0.1 kg and 0.1 cm, respectively. Waist circumference will be measured midway to the lowest rib and the top of the iliac crest after gentle expiration; weight will be measured with a digital scale. The anthropometric data will be expressed as the mean of two measurements.
2. Satiation and satiety assessed using the Visual Analogue Scale questionnaire
3. Collection of faecal samples at baseline and after 2 weeks, 4 weeks and 12 weeks for:
3.1. Gut microbiota composition defined by 16S rRNA gene profiling on DNA extracted
3.2. Characteristics of the stool identified through the Bristol Stool Scale (BSS)
3.3. Short-chain fatty acids identified in faecal samples through qualitative and quantitative analysis in gas chromatography and pH measuring
3.4. Intestinal permeability and inflammatory processes investigated through the dosage of serum zonulin and faecal calprotectin through the ELISA test

Completion date
15/10/2022

Eligibility

Key inclusion criteria
1. Obesity (BMI ≥35 kg/m²) with or without comorbidities
2. 18 to 65 years of age
3. Dysglycemia, altered fasting glycemia or insulin resistance (HOMA index >2.5)
4. Possibility to be followed in the follow up at Auxologico Via Ariosto (Milan)
5. Negative swab for COVID-19 at enlistment

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Type 1 and 2 diabetes in treatment
2. Previous operations of bariatric surgery
3. Psychiatric illness
4. Inflammatory bowel disease
5. Untreated thyroid
6. Past or present history of malignant neoplasia

Date of first enrolment
15/04/2021

Date of final enrolment
15/04/2022

Locations

Countries of recruitment
Italy

Study participating centre
San Giuseppe Hospital - Piancavallo
Via Cadorna 90

Oggebbio
Italy
28824

Study participating centre
San Michele Hospital
via Ariosto 13
Milano
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Sponsor information

Organisation
Istituto Auxologico Italiano

ROR
https://ror.org/033qpss18

Funder(s)

Funder type
Government

Funder Name
Istituto Auxologico Italiano

Alternative Name(s)
Auxologico

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Italy

Funder Name

Regione Lombardia

Alternative Name(s)
Lombardy Region, Region of Lombardy

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Italy

Funder Name
Indena

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 Sara Mambrini (s.mambrini@auxologico.it), a.bruno@auxologico.it; Simona Bertoli (simona.bertoli@unimi.it), Massimo Scacchi (massimo.scacchi@unimi.it). Data of the markers analysed will be available upon request at the end of the study. Data are anonymous and consent from participants was obtained.

IPD sharing plan summary
Available on request