

# Effect of a bean extract on glucose metabolism in obesity

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<b>Registration date</b> 20/05/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 20/05/2021	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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/m<sup>2</sup> 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?

Prof. Massimo Scacchi, massimo.scacchi@unimi.it

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## Additional identifiers

### Clinical Trials Information System (CTIS)

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. Satiety 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  $\geq 35$  kg/m<sup>2</sup>) 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

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Italy

28824

**Study participating centre**  
**San Michele Hospital**  
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Milano  
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20145

## 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