

# The effect of selenium supplementation alongside a balanced low-calorie diet in patients with obesity

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<b>Registration date</b> 15/04/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 23/06/2020	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Some studies have found that obese people have a selenium deficiency. Depression, which is often present in obese people, also appears to be affected by dietary selenium intake. Taken together, these findings suggest a promising role for selenium supplementation in obese people. Hence this study aimed to assess the effect of selenium supplementation on body weight and mood in obese subjects.

### Who can participate?

Patients aged 18 to 65 with a BMI  $\geq$  25 referred to the Endocrinology Unit for weight loss

### What does the study involve?

Participants will have an interview with a clinical nutritionist and are given information about the study. They will follow a slightly hypocaloric diet for 3 months, where they do not to change their usual physical activity levels.

Participants will also be given either selenium or a placebo as a gel formula to take over the 3 month study period.

At the beginning and end of treatment, participants will have blood tests for hormone levels, measurement of weight and body composition, and a questionnaire to measure mood.

### What are the possible benefits and risks of participating?

Participants may experience benefits in their mood and weight. No risks are expected for participants due to the short period of intake and the daily dose of selenium.

### Where is the study run from?

Endocrinology Unit, University of Padua (Italy)

### When is the study starting and how long is it expected to run for?

From May 2014 to May 2016

Who is funding the study?  
The University of Padua (Italy)

Who is the main contact?  
Prof Caterina Mian  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**Protocol serial number**  
Protocol No. 3220/AO/14

## Study information

**Scientific Title**  
Selenium supplementation, body mass composition and leptin levels in patients with obesity on a balanced, slightly hypocaloric diet

**Acronym**  
LOWT3SYNDROME

**Study objectives**  
This is a pilot study that aims to assess the effect of high-dose selenium supplementation on body weight, leptin levels and mood in a selected group of patients with obesity adopting a balanced, slightly hypocaloric diet as part of a single-center randomized controlled trial

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**

Approved 26/02/2015, the Ethical Committee for Clinical Trials in the Province of Padua (Via Giustiniani, 2, 35128 Padua, Italy; +39 049 8212341 - 42; ce.sperimentazione@aopd.veneto.it), ref: 3220/AO/14

**Study design**

Single-blind, two-arm, randomised controlled pilot study

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Overweight/obesity

**Interventions**

This randomized prospective study will include about 40 overweight/obese individuals aged 18-65 years, who will follow a slightly hypocaloric diet for 3 months. Participants were asked not to change their usual physical activity during the study period.

Participants will first have an interview with a clinical nutritionist and are given information about the study. Participants will be randomly allocated to one of two single-blind groups. The intervention group will take 240 µg/day of L-selenomethionine in a soft gel formula, divided into several daily doses, for 3 months. The control group will take a placebo also delivered in a soft gel formulation at the same frequency. The randomization process was web-based and computer-generated ([www.Randomization.com](http://www.Randomization.com))

At the beginning and end of treatment, clinical and biochemical parameters such as leptin levels and thyroid function, body composition, and mood using the Psychological General Well-Being Index (PGWBI) questionnaire will be measured.

**Intervention Type**

Supplement

**Primary outcome(s)**

Body mass composition will be assessed with a bioelectrical impedance analysis (BIA) using the Biavector® nomogram and Bodygram™ software (Akern Bioresearch s.r.l.), recording values for lean mass, fat mass, and muscle mass at baseline and 3 months

**Key secondary outcome(s)**

1. Leptin levels will be assessed using blood samples taken at baseline and 3 months
2. Weight will be measured during clinical assessment at baseline and 3 months
3. Mood will be assessed using the Psychological General Well-Being Index (PGWBI) questionnaire at baseline and 3 months
4. Thyroid function will be assessed using blood samples taken at baseline and 3 months

**Completion date**

31/07/2016

# Eligibility

## Key inclusion criteria

1. Body mass index (BMI)  $\geq 25$  kg/m<sup>2</sup>
2. Aged 18-65 years
3. Referred to the Endocrinology Unit of the University of Padua for the purpose of losing weight

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Adult

## Lower age limit

18 years

## Upper age limit

65 years

## Sex

All

## Total final enrolment

37

## Key exclusion criteria

1. Smoking
2. Treatment with levothyroxine or any medication modifying thyroid function (e.g. corticosteroids, amiodarone, propranolol, lithium)
3. TSH levels outside the normal laboratory range
4. Severe cardiopathy treated with antiarrhythmics or vasodilators
5. Pregnancy or breastfeeding; previous or current malignancies
6. Severe eating disorders
7. Liver failure
8. Pharmacological treatment for obesity
9. Chronic inflammatory disease

## Date of first enrolment

29/01/2015

## Date of final enrolment

29/06/2016

# Locations

## Countries of recruitment

Italy

**Study participating centre**

**University of Padua**  
Endocrinology Unit  
Department of Medicine  
University of Padua  
Via Ospedale civile n.105  
Padova  
Italy  
35128

**Sponsor information****Organisation**

University of Padua

**ROR**

<https://ror.org/00240q980>

**Funder(s)****Funder type**

University/education

**Funder Name**

Università degli Studi di Padova

**Alternative Name(s)**

University of Padova, University of Padua, UNIPD

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Universities (academic only)

**Location**

Italy

**Results and Publications**

## Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication

## IPD sharing plan summary

Data sharing statement to be made available at a later date

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	28/05/2020	23/06/2020	Yes	No