

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

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 15/04/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 23/06/2020	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<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  
caterina.mian@unipd.it

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Caterina Mian

**ORCID ID**  
<http://orcid.org/0000-0003-2615-8001>

**Contact details**  
University of Padua  
Via ospedale civile 105  
Padova  
Italy  
35128  
+39 0498213003 04 00  
caterina.mian@unipd.it

## Additional identifiers

**EudraCT/CTIS number**  
Nil known

**IRAS number**

**ClinicalTrials.gov number**  
Nil known

**Secondary identifying numbers**  
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

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet

**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 measure**

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

**Secondary outcome measures**

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

**Overall study start date**

09/05/2014

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

65 Years

**Sex**

Both

**Target number of participants**

40

**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

**Sponsor details**

via ospedale civile 105

Padua

Italy

35128

+39 049 821 3003

caterina.mian@unipd.it

**Sponsor type**

University/education

**Website**

<http://www.unipd.it/en/home-page>

**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

**Publication and dissemination plan**

We intend to publish the results in a peer-reviewed journal

**Intention to publish date**

07/05/2017

**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?
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[Results article](#)

results

28/05/2020

23/06/2020

Yes

No