ISRCTN61060735 https://doi.org/10.1186/ISRCTN61060735

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

Submission date
09/04/2020

Recruitment status
No longer recruiting

Registration date
15/04/2020

Overall study status
Completed

Last Edited
23/06/2020

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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 ≥ 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?
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Contact information

Type(s)
Scientific

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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

Primary study design
Interventional

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

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)

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) ≥25 kg/m2
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?
Results article	results	28/05/2020	23/06/2020	Yes	No