Vitamin D3 in Obesity: Identification of Central Nervous System Targets Using High-Technology Functional MRI

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26821

Source
Nationaal Trial Register

Brief title
D-LIGHTFUL

Health condition

Obesity

Sponsors and support

Primary sponsor: Investigator initiated trial
Source(s) of monetary or material Support: Investigator initiated trial

Intervention

Outcome measures

Primary outcome

The effects of calcitriol on neuronal activity in brain areas involved in food intake using functional magnetic resonance imaging (fMRI) in lean and obese subjects.

Secondary outcome

The differences in calcitriol-induced dopaminergic effects between lean and obese participants and the effects of calcitriol on satiety, energy metabolism, and food-related behavior (questionnaires) in association with changes in fMRI responses.

Study description

Background summary

Obesity and obesity-related complications are associated with reduced quality of life and increased social and healthcare-related costs. Altered brain dopamine signaling has been implicated in the development and progression of obesity. Recent evidence from animal studies showed that calcitriol treatment increases dopamine release and reduces food intake and body weight. Whether this is similar in humans has not been experimentally explored. Therefore, we will perform a study to investigate the effects of calcitriol on neuronal activity in brain areas involved in food intake using functional magnetic resonance imaging (fMRI) in lean and obese subjects.

Study objective

After calcitriol treatment, i. resting state striatal neuronal activity, i.e. BOLD signal, is increased and ii. visual food stimuli-induced neuronal activity of brain areas involved in food intake is reduced.

Study design

Both study interventions will be scheduled approximately one week after each other and will each be followed by two additional safety monitoring blood draws.

Intervention

This study consists of two interventions involving one calcitriol and one placebo (saline) infusion (order determined upon randomization).

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
 Age between 18 – 35 years;
 Capability to provide informed consent;
 Stable weight (<5% change) for 3 months prior to study assessment.

Additionally, for the obese subset:
 BMI between 30 – 40 kg/m2;
 Metabolically unhealthy, defined as fasting plasma insulin levels >74 pmol/l at screening (89).

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
 Any medical disorder (with the exception of metabolic syndrome and other obesity-related disorders in the obese subset);
 Childhood-onset obesity;
 Contraindication to MRI scanning (e.g. claustrophobia, pacemaker, metal IUD);
 Participants who skip their breakfast or work in shifts;
 Serum 25-hydroxyvitamin D (25(OH)D) concentrations below 50 nmol L−1;
 Significant sensory or motor impairment;
 Subjects taking any medication except for medication for obesity-related metabolic disorders (excluding diabetes treatment)
 Subjects who cannot adhere to the experimental protocol for any reason;
 The use of weight loss agents or use within 3 months prior to study;
 Weight loss surgery or gastrectomy.
 Hypercalciemia at screening

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-02-2019
Enrollment:	30
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	20-02-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7536
Other	METC AMC : METC2018_101

Study results