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

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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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26821

Bron
Nationaal Trial Register

Verkorte titel
D-LIGHTFUL

Aandoening

Obesity

Ondersteuning

Primaire sponsor: Investigator initiated trial
Overige ondersteuning: Investigator initiated trial

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	04-02-2019
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	20-02-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7536
Ander register	METC AMC : METC2018_101

Resultaten