Effects of seaweed on blood glucose

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We hypothesize that dietary supplementation with seaweed will improve glucose regulation in T2DM patients.

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

Samenvatting

ID

NL-OMON20760

Bron
NTR

Verkorte titel
TBA

Aandoening

diabetes type 2

Ondersteuning

Primaire sponsor: Erasmus Medical Center
Overige ondersteuning: Health Holland

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Difference between the mean blood glucose levels measured during the first week of usual diet and during week 2 to 6 when daily seaweed is consumed.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Type 2 diabetes mellitus (T2DM) is a serious highly prevalent (> 1 million in the Netherlands) chronic disease and its complications, cardiovascular disease, retinopathy, nephropathy, neuropathy, and foot amputation lead to premature death. Therefore there is an urge for prevention. Because diet plays an important role in the development of T2DM, dietary interventions may provide solutions. Seaweeds contain unique bioactive components that improve glucose tolerance and also circulating lipid levels.
Objective: To determine if dietary supplementation with seaweed improves glucose regulation in T2DM patients.
Study design: This is a randomized placebo-controlled study to be conducted in three parallel study arms for 6 weeks.
Study population: Sixty eligible patients with T2DM and a BMI > 25 will be enrolled. The study will be performed in patients with T2D and a BMI>25
The participants are allowed for inclusion in the study only after written informed consent and approval by our Medical Ethical Review Board. Exclusion criteria are type 1 or monogenetic forms of diabetes, thyroid disease, pregnancy use of blood coagulants and corticosteroids, heart failure and recent myocardial infarction The participants are allowed for inclusion in the study only after written informed consent and approval by our Medical Ethical Review Board.
Intervention (if applicable): Patients will receive either 5 gram of Sargassum fusiforme (Sargassum), Fucus vesiculosus (Fucus) or placebo (0.5 gram Nori) during 5 weeks (week 2-6). Clinical information (anamnesis and physiological examination) and blood sampling will be performed at the start of the study, 1 week and after 6 weeks of the study. One week before start of the treatment and during treatment blood glucose will be monitored continuously by a device, that will be replaced weekly, blinded for the participants.
This study will be conducted in compliance with Good Clinical Practices (GCP) and ICH guidelines
Main study parameters/endpoints: Main study parameters/endpoints: Difference between the mean blood glucose levels measured during the first week of usual diet and during week 2 to 6 when daily seaweed is consumed.
Secondary outcomes are differences between week 1 and week 6 in terms of body weight (kg) because seaweed consumption can contribute to weight loss; HbA1c and total daily insulin use, and fasting blood glucose levels (Mmol/L) in addition to the continuously monitored glucose levels. Levels of total cholesterol, LDL-cholesterol, HDL-cholesterol, lipoprotein (a) (g/L), apoB100/48 (Mmol/L) and triglycerides (Mmol/L) (measured using routine laboratory analysis) will be analyzed, and pulse wave velocity and blood pressure (mmHg) and cytokines.

Doel van het onderzoek

We hypothesize that dietary supplementation with seaweed will improve glucose regulation in T2DM patients.

Onderzoeksopzet

baseline (week 1) - week 2-6 (continuous glucose monitoring)

Onderzoeksproduct en/of interventie

Patients will receive either 5 gram of Sargassum fusiforme (Sargassum), 5 gram of Fucus vesiculosus (Fucus) or placebo (0.5 gram Nori) during 5 weeks (week 2-6).

Contactpersonen

Publiek

Erasmus MC
Kirsten Berk

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Patients with T2DM and BMI>25
- All adults; age ≥ 18 years
- Diabetes based on criteria of ADA

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Type 1 or monogenetic forms of diabetes.
- Thyroid disease

- Pregnancy
- Usage of corticosteroids
- Usage of blood anti-coagulants
- History of heart failure or recent myocardial infarction within 3 months
- Transplantation
- Allergy for shellfish

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	13-05-2019
Aantal proefpersonen:	60
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:	30-08-2019
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	NL7987
CCMO	NL66189.078.18

Resultaten