Effects of seaweed on blood glucose

Published: 30-08-2019
Last updated: 10-01-2025

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

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

Summary

ID

NL-OMON20760

Source
Nationaal Trial Register

Brief title
TBA

Health condition

diabetes type 2

Sponsors and support

Primary sponsor: Erasmus Medical Center
Source(s) of monetary or material Support: Health Holland

Intervention

Outcome measures

Primary outcome

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 outcome

differences between week 1 and week 6 in terms of body weight (kg); 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.

Study description

Background summary

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.

Study objective

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

Study design

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

Intervention

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).

Contacts

Public
Erasmus MC
Kirsten Berk

0617512121
Scientific
Erasmus MC
Kirsten Berk

0617512121

Eligibility criteria

Inclusion criteria

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

Exclusion criteria

- 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

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-05-2019
Enrollment:	60
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	30-08-2019
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	NL7987
CCMO	NL66189.078.18

Study results