Potential of seaweed in reducing blood glucose of obese type 2 diabetes patients

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To determine if dietary supplementation with seaweed improves glucose regulation in T2DM patients.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Diabetic complications
Study type	Interventional

Summary

ID

NL-OMON48790

Source
ToetsingOnline

Brief title
Effects of seaweed on blood glucose;"EndT2D""

Condition

- Diabetic complications

Synonym
type 2 diabetes, type 2 diabetes mellitus

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Medical Meals,Medtronic,Ocean University of China,Seaweed Harvest Holland,Stichting Zeeschelp,TKI-LSH HHINT Kickstarter for PPP;Seaweed Harvest Holland;Stichting Zeeschelp;Medical Meals;Ocean University of China

Intervention

Keyword: blood glucose, seaweed, type 2 diabetes

Outcome measures

Primary outcome

The primary outcome is the difference between the mean blood glucose levels measured during the first week of usual diet and during the last 5 weeks of daily seaweed consumption. Effects of seaweed will be compared with the effect of placebo. Blood glucose will be monitored continuously by a device (Medtronic, Eindhoven) blinded for the participants.

Secondary outcome

Examine if Sargassum or Fucus supplementation results in bodyweight reduction and in improvement of risk factors for cardiovascular disease (CVD). Secondary outcomes are differences between week 1 and week 6 in terms of:

* Body weight, Glucose, HbA1c, total daily insulin use,

* Body weight, body mass index, waist-to-hip ratio, blood pressure, plasma lipids and peripheral blood phagocyte inflammatory activation status and ability to generate pro-angiogenic accessory cells from blood monocytes.

Study description

Background summary

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, because of its extreme growth conditions, contain unique

bioactive components that improve glucose tolerance and also circulating lipid levels.

Study 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.
Researchers and participants will be blinded for the researchproduct the participants receive.

Intervention

Patients will receive either 5 gram of Sargassum fusiforme (Sargassum), Fucus vesiculosus (Fucus) or placebo (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 and that is blinded for the participants. In week 1, 3 and 6 food intake will be recorded in a diary.

Study burden and risks

The risk is estimated as low.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

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

Exclusion criteria

-Type 1 or monogenetic forms of diabetes.
- Thyroid disease
- Pregnancy
- Usage of corticosteroids
- Usage of blood coagulants
- History of heartfailure or recent myocardial infarction within 3 months
- Transplantation

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

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

Ethics review

Approved WMO Date:	20-12-2018
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	18-03-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-07-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL66189.078.18