

Iodine bioavailability from seaweed

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We expect higher bioavailability of seaweed types containing more inorganic iodine, compared to seaweed types containing more organic iodine.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aanpak	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24940

Bron

NTR

Verkorte titel

TBA

Aandoening

iodine excess

Ondersteuning

Primaire sponsor: Direct funding

Overige ondersteuning: direct funding

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome measures will be 24-h urinary iodine excretion (UIE), fecal iodine excretion (FIE) and the iodine intake, expressed as $\mu\text{g/d}$. The UIE will be calculated at each of the 3 balance days at all 3 test weeks ($n=108$). The FIE will be calculated for 2-days after ingestion of the test meal, and once prior to the ingestion of the test meal in order to control for iodine excretion from the standardized diet. The iodine intake is based on the iodine

concentration of the standardized diet and the test meal. The sum of the UIE and the FIE results in the total iodine excretion (TIE). However, in order to correct for the iodine excretion of the standardized diet, the UIE of the first day of the balance periods and the FIE at day 1 and 2 of the first week will be used to calculate the contribution of the standardized diet to the TIE.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Iodine is an essential component of thyroid hormones, and both deficient and excessive dietary intake of iodine can lead to disturbances in thyroid metabolism. The dietary reference intake for an adult is 150 µg/d, whereas the upper level of intake is 600 µg/d. Dietary iodine is generally well absorbed and is estimated at 90% of intake with little difference between organic and inorganic iodine (Hurrell, 1997), although little is known about organically bound iodine. One of the issues that is so far unknown is the bioavailability of iodine from edible seaweeds. Seaweed is generally correlated with high iodine intake, but the amount and composition of organic(-ally bound) and inorganic iodine in different seaweed species varies. Furthermore, complex plant structures of some seaweed species could result in poor release of iodine during digestion (Katamine et al. 1987). This suggests that there may be differences in iodine bioavailability between seaweed species that can have implications for safety of its consumption in terms of potential harmful effect on the thyroid.

Primary objective: To conduct iodine bioavailability of two seaweed products available in stores, *Palmaria palmata* and *Fucus vesiculosus*, in humans compared to potassium iodide (KI). **Secondary objective:** To compare the 24-h urine collection of urinary creatinine excretion with PABA based on prediction of muscle mass.

Study design: We will conduct a 3-week, randomized, crossover balance study in adults (n=12) who will consume three test meals with a comparable iodine content. The test meals, each 1 week apart, will be administered in random order with a crossover design. Each study week consists of a 4-day wash-out period, followed by a 3-day balance period with a standardized diet.

Study population: Healthy human volunteers who are iodine sufficient, aged 18-45 with a normal BMI of 18.5-25 kg/m².

Intervention (if applicable): All subjects will receive three test meals with a different type of seaweed, and an iodine supplement (1 each week). Both the test meals and the supplement will contain 400 µg of iodine. The test meal will be administered in the morning on the 2nd day of each balance period after an overnight fast.

Main study parameters/endpoints: The main study parameter is the ratio between the 24-h urinary iodine excretion (UIE) and the iodine intake of the test meal, after correction for the iodine intake and excretion of the standardized diet. Herewith, the iodine bioavailability of the two seaweed species can be calculated and compared to the supplement.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: We do not anticipate that the study will cause any harm to the subjects, apart from occasional bruising upon venous blood collection. Blood collection will be carried out by

trained and experienced study nurses to minimize the burden. The seaweed food products provided to participants are normal commercially available foods, and iodine intake will not exceed the safe upper level.

Doel van het onderzoek

We expect higher bioavailability of seaweed types containing more inorganic iodine, compared to seaweed types containing more or organic iodine.

Onderzoeksopzet

3-week intervention. once a week, the subjects will receive a meal with seaweed or KI in random order.

Onderzoeksproduct en/of interventie

We will conduct a 3-week + 1 day, randomized, crossover balance study in adults (n=10) who will consume three test meals with a comparable iodine content: 1) seaweed product 1 (SWD1); 2) seaweed product 2 (SWD2); and 3) iodine supplement (SPL). The three test conditions, each 1 week apart, will be administered in a random order with a crossover design. A crossover design is chosen in this study, since it removes inter-subject variation and results in a greater precision of the estimated bioavailability. Each study week consists of a wash-out period of 4 days to eliminate the effect of previous iodine intake, followed by a 3-day or 4-day balance period. During the wash-out period, participants are asked to follow their usual food habits, while avoiding the consumption of products very high in iodine, marine fish and seaweed, and limit their alcohol consumption.

In the balance period, the participants will receive a 3-day or 4-day standardized diet with an iodine content below 100 µg/day. The test meal will be administered in the morning on the 2nd day (week 2 and 3) or 3rd day (week 1) of each balance period after an overnight fast. The test meals will be administered in a random order. Breakfast will be provided one hour after consuming the test meal. Participants are not allowed to do intensive sports that could cause excessive sweating, since iodine can be excreted in sweat.

The participants will collect all their urine during the 3-day balance period. At the first week of the study, urine will be collected from the 1st until the 4th day of the balance period. Participants will collect their feces for two days starting at 12:00 after the ingestion of each test meal for 48 hours. In order to distinguish between iodine in feces from the standardized diet (baseline) and the test meal, the participants will also collect feces at the first 2 days of the balance period in week 1.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Age: 18-45 years

BMI: 18.5-25 kg/m²

Mean urinary iodine concentration 100-300 mcg/L of 5 spot samples (5 different days)

Normal thyroid hormone levels (Normal hormone levels are 0.4-4.0 mIU/L for TSH, 58-161 nmol/L for total T4 and ≤ 55 ng/mL for thyroglobulin)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- History of thyroid, metabolic, gastrointestinal or chronic diseases
- Chronic use of medication (except oral contraceptives)
- Use of iodine containing skin creams/products within the last month
- Use of iodine supplements within the last month
- Exposure to iodine containing X-ray/computed tomography contrast agents within the last six months
- Excess alcohol intake (defined as > 3 (men) or 2 (women) standard drinks per day)
- Smoking
- Consuming a vegan diet
- Pregnant or lactating

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-02-2021
Aantal proefpersonen:	10
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing	
Soort:	Niet van toepassing

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

NTR-new

Ander register

ID

NL9088

METC WU : 20/19

Resultaten