Iodine bioavailability from seaweed

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24940

Source
NTR

Brief title
TBA

Health condition

iodine excess

Sponsors and support

Primary sponsor: Direct funding
Source(s) of monetary or material Support: direct funding

Intervention

Outcome measures

Primary outcome

The primary outcome measures will be 24-h urinary iodine excretion (UIE), fecal iodine excretion (FIE) and the iodine intake, expressed as µg/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.

Secondary outcome

Secondary outcome measures will be the urine completeness of the participants at all 10 days of the balance period. At the first balance day, the PABA recovery will be measured based on the ingestion of 3 PABA tablets (1 at each meal). If the recovery of PABA is below 85%, the 24-h urine collection is incomplete. During the other 9 balance days, the urine completeness will be calculated by the urinary creatinine excretion. Since creatinine is constantly excreted by the muscles, the muscle mass of the participants will be measured with BIA. If the creatinine index is below 0.7, the 24-h urine collection is incomplete. Incomplete urine collections cannot be used in the study, so will be excluded.

Study description

Background summary

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.

Study objective

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

Study design

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

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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)

Exclusion criteria

-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

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2021
Enrollment:	10
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

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	NL9088
Other	METC WU : 20/19

Study results