Determination of the iodine status in pregnant women in the Netherlands. Are current iodine intake recommendations still adequate?

Published: 08-05-2020
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To determine iodine deficiency in pregnant women in the Netherlands.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON52954

Source
ToetsingOnline

Brief title
Iodine status in pregnancy

Condition

- Other condition

Synonym
iodine deficiency, iodine intake

Health condition

tekort aan micronutrienten tijdens de zwangerschap (in dit geval jodium)

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: RIVM

Intervention

Keyword: iodine, jodiuminname, pregnany

Outcome measures

Primary outcome

The main outcome is the median urinary iodine excretion (µg/d) in pregnant

women in the Netherlands in relation to serum Tg (µg/l).

Secondary outcome

• Thyroglobulin and thyroglobulin antibody concentrations in blood serum

• Creatinin concentration in urine

• Urinary volume

• Smoking status (smoking is interfering with iodine metabolism)

• Vegan/Vegetarian y/n (soy is competitive for iodine on thyroid)

• Nutritional intake specifically related to iodine intake (questionnaire)

• Intake other relevant micronutrients for pregnant women from supplement use

(vitamin D, folate, calcium; questionnaire)

Other study parameters/endpoints:

• Pre-pregnancy body weight (self-reported)

• Height (self-reported)

• BMI

• Educational level

• Age

• Ethnicity

• Parity

Study description

Background summary

Adequate dietary iodine intake is essential to thyroid hormone synthesis, which is key for normal growth, development and metabolism. During pregnancy, maternal iodine needs are increased and iodine deficiency during pregnancy might lead to pregnancy complications and can affect brain and cognitive development of the foetus. Despite iodine fortification programs, it has been shown that iodine intake in the Netherlands is declining, implicating that also pregnant women are at risk for iodine deficiency. Low median urinary concentrations of iodine (81-124 ug/L) in pregnant women have been shown in several other Western European countries (i.e. Belgium, U.K., Sweden, Denmark and Austria). However, except for a small pilot study in Groningen that indicated a high prevalence of iodine deficiency during pregnancy (83%), no data on iodine intake during pregnancy are available in the Netherlands. Notably, most studies collected spot-urine samples whereas the golden standard for determination of iodine status is lacking. Therefore, here we propose to detemine iodine deficiency during pregnancy in a larger Dutch population, using the golden standard technique of a 24h urine collection combined with serum thyroglobulin concentrations.

Study objective

To determine iodine deficiency in pregnant women in the Netherlands.

Study design

This is an observational study to detemine the iodine status of pregnant women in The Netherlands.
To this end, we will measure the 24h median urinary iodine concentration corrected for urinary volume and creatinin levels in pregnant women, and compare these values with Thyroglobulin (Tg)-concentrations in serum (as measure for iodine intake over a longer period of time). To collect thes data, women will visit the research center for a single blood draw (15ml), collect urine for 24h at home and fill out a food-intake questionnaire specific for iodine-rich foods/supplements.

Study burden and risks

Data collection includes a single blood collection (max 15 ml), which might cause some discomfort at the needle insert. A small bruise around the site of insertion might occur, which will disappear within 1-2 days. The 24h urine collection is not related to any health risk. Collecting all urinary samples during 24 hours requires some effort and dedication of the participants. Materials will be provided including a decent shopper/bag for discretely carrying around of urine containers. Questionnaires on demographics and food intake specific for iodine-rich food items and are not considered to be burdensome.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Inclusion criteria

- Female
- 18-45y old
- before 16 weeks of pregnancy

- Pregnant of singleton

Exclusion criteria

- thyroid-disease or any other metabolic disease
- twin-pregnancy
- kidney disease

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-10-2020
Enrollment:	96
Type:	Actual

Ethics review

Approved WMO Date:	08-05-2020
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	06-12-2022
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 22754
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL70677.068.19
Other	NL8297