Insights into the pathophysiology of HAshimoto’s Thyroiditis: Assessing Residual thyroid cApacity & the role of the gut Microbiome in thyroid hormone metabolism

No registrations found.

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

Summary

ID

NL-OMON22728

Source
NTR

Brief title
ARGOS trial

Health condition

subclinical hypothyroidism

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Amsterdam UMC

Intervention

Outcome measures

Primary outcome

To assess and compare the difference in thyroid gland secretion capacity by measuring maximal FT4 and FT3 response upon intramuscular administration of 0.9mg Thyrogen assessed by AUC0-48hours in subclinical hypothyroid subjects and healthy controls after thyroid stimulation and before and after a short term antibiotics course.

Secondary outcome

Secondary objectives will be influence of gut microbiome on thyroid hormone metabolism and effect of thyroid hormone stimulation on inflammatory status after thyroid stimulation and before and after a short term antibiotics course.
- Gut microbiome composition:
- To assess and compare changes in the gut microbiome composition between SCT subjects and healthy controls at baseline.
- In addition, microbiota composition (and their plasma metabolites) will be determined and compared upon thyroid hormone stimulation and before and after a short term oral antibiotics course.

- Thyroid hormone metabolism:
- To assess and compare changes of fecal excretion of T4 and T3 in SCT subjects and healthy controls before and after thyroid hormone stimulation.
- In addition, we will determine changes of fecal excretion of T4 and T3 before and after a short term antibiotics course.
- Quality of life will be determined by ThyPro questionnaire
- Immunologic parameters: based on FACS on peripheral blood mononuclear cells (Th1, Th2, Th17, Treg, B cells), cytokines and markers of thyroid autoimmunity (anti-TPO antibodies) in SCT subjects as compared to healthy controls at 0h, 5h and 48h after thyroid stimulation and before and after a short term antibiotics course.
- Intestinal transit time
- Evaluate the differences of intestinal transit time as assessed by radiopaque makers between SCT subjects and healthy controls.

Study description

Background summary

A better understanding of the (patho)physiological pathway of the gut microbiome involvement in thyroid hormone metabolism and residual thyroid function in autoimmune hypothyroidism is needed . in this study we aim to validate a dynamic thyroid function test to assess thyroid reserve capacity (by measuring maximal serum FT4 and FT3 response upon a single intramuscular administration of 0.9 mg r-TSH). Moreover, we aim to evaluate the effect of the gut microbiome changes on thyroid hormone metabolism in subclinical autoimmune hypothyroid subjects by assessing and comparing changes of plasma and faecal levels T4 and T3 upon the Thyrogen stimulation and a short course of antibiotics in 20 subjects (10 subclinical autoimmune hypothyroid patients (medication naïve) and 10 matched healthy

controls).

Study objective

residual thyroid function is altered by short term oral antibiotic treatment in subclinical hypothyroid subjects as compared to healthy controls.

Study design

day 0-2 and 21-23 (reproducibility of residual thyroid function test) as well as after oral antibiotics (day 44-46)

Intervention

rTSH injections for residual thyroid function. Moreover, one week with oral metronidazole (500 mg twice daily) plus ciprofloxacin (500 mg once daily), plus oral vancomycine (500mg four times daily).

Contacts

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Eligibility criteria

Inclusion criteria

Healthy controls:
- Caucasian
- 35 – 70 years
- BMI 18 – 30 kg/m2
- Able to give informed consent

subclinical hypothyroidism:
- Caucasian
- 35 – 70 years
- BMI 18 – 30 kg/m2
- Able to give informed consent
- Recent diagnosis of subclinical hypothyroidism: TSH ≥ 10 mU/L, FT4 within normal range and anti-TPO positive

Exclusion criteria

For all subjects:
- Use of any medication including levothyroxine, proton pump inhibitors, antibiotics and pro-/probiotics in the past three months
- Diagnosis or symptoms of other autoimmune disease (e.g. T1D, coeliac, rheumatoid arthritis or inflammatory bowel disease like Crohn and colitis ulcerosa)
- History of cholecystectomy
- Smoking or illicit drug use (MDMA/amphetamine/cocaine/heroin/GHB) in the past three months or use during the study period
- Pregnant or lactating women
- Previous intestinal (e.g., bowel resection/reconstruction) surgery
- Chronic illness (including a known history of heart failure, renal failure (eGFR <30 ml/min), pulmonary disease, gastrointestinal disorders, or hematologic diseases), or other inflammatory diseases

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2020
Enrollment:	20

Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
n/a

Ethics review

Positive opinion

Date:	24-09-2020
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	NL8925
Other	METC AMC : 2020-140

Study results

Summary results
will follow