

The influence of metformin and a hypocaloric diet on thyroid radioactive iodide uptake in healthy volunteers: a pilot study

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use of metformin and a hypocaloric diet result in reduced thyroid iodide uptake.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28976

Bron

Nationaal Trial Register

Verkorte titel

thyroid iodide uptake study 1

Aandoening

thyroid disease

Ondersteuning

Primaire sponsor: Radboud University Medical Centre Nijmegen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Thyroid I-123 uptake.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Treatment with radioactive iodide (RAI) is a widely used and highly efficient treatment for

benign and malignant thyroid diseases, such as differentiated thyroid cancer (TC). Specific thyroid

iodide uptake is needed to assure effective RAI treatment in TC, which is facilitated by the expression

of a sodium-iodide symporter (NIS) on the thyroid cell. Factors that influence either positively or

negatively the NIS expression and function could affect the response to RAI treatment. It has been

shown that that activation of AMP-activated- protein-kinase (AMPK) leads to decreased NIS

expression and iodide uptake in in vitro studies and animal models. For this reason we will focus in

this study on modulators of AMPK activity in relation to thyroid iodide uptake in humans. The first

important modulator of AMPK is metformin, a well known drug in the treatment of type 2 diabetes

mellitus (DM). Because there is evidence that thyroid disease and DM are closely linked and

metformin is investigated as important adjunct in the treatment of TC, we estimate that there is a

large group of patients that use metformin who undergo RAI treatment, making it interesting to

investigate the effects of metformin on thyroid iodide uptake. Secondly, we want to investigate the

effects of a hypocaloric diet, since hypocaloric conditions also induce AMPK activation. During RAI

treatment for TC, patients undergo thyroid hormone withdrawal or administration of rhTSH to stimulated thyroid iodide uptake. Thyroid hormone withdrawal results in symptomatic

hypothyroidism, leading to complaints such as weight gain and nausea, which could result in reduced

food intake and thus hypocaloric conditions. Since this could influence AMPK activation and thus

thyroid iodide uptake and RAI efficacy, it is relevant to investigate the effect of altered caloric intake

on thyroid iodide uptake.

Objective: To assess the physiological effects of metformin and hypocaloric dieting on thyroid iodide

uptake and thyroid function in healthy volunteers.

Study design: This is an investigator initiated interventional pilot study.

Study population: 17 healthy male volunteers, aged 18-50 years.

Intervention: The first group of 7 subjects will follow a two week course of metformin according a

specific dosing scheme and follow an iodide restricted diet. Group 2 with 7 subjects will follow a

hypocaloric diet (40% caloric restriction, high fat, low carbohydrate content) with an iodide restricted

diet for two weeks. There will be a control group of 3 subjects to assess the degree of intra-individual variation in thyroid iodide uptake, who will only follow a iodide restricted diet.

Main study parameters/endpoints: Primary endpoint is the change observed in ^{123}I thyroid uptake

measured by Radioactive iodide uptake testing (RAIU) before and after either metformin or

hypocaloric dieting. Secondary endpoints are the changes in serum levels of TSH, fT4 and T3 before

and after intervention.

Doel van het onderzoek

use of metformin and a hypocaloric diet result in reduced thyroid iodide uptake.

Onderzoeksopzet

- 2 week course of iodide restricted diet, followed by baseline measurements of thyroid function and thyroid radioactive iodide uptake

- 2 week intervention period, followed by measurements of thyroid function and thyroid radioactive iodide uptake after intervention

Onderzoeksproduct en/of interventie

group1: 2 week course of metformin and iodide restricted diet

Group 2: 2 week course of hypocaloric, iodide restricted diet

Groep 3 (control group): 2 week course of iodide restricted diet

Contactpersonen

Publiek

Radboud UMC

Yvette Sloot
Nijmegen
The Netherlands

Wetenschappelijk

Radboud UMC

Yvette Sloot
Nijmegen
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- . male
- . No mental illness
- . Informed consent
- . Healthy, specifically no history of thyroid disease or renal insufficiency
- . Aged between 18-50 years
- . Normal weight (BMI: '18.5-25.0 kg/m²)
- . Maintained stable body weight for previous 6 months

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- . Mentally incompetent
- . Any thyroid condition: hypo- or hyperthyroidism, thyroid cancer, other thyroid conditions.
- . Any chronic illness, including diabetes mellitus, acute or chronic infections, other disease requiring treatment.
- . Use of any medication or homeopathic medications. Use of paracetamol is allowed.
- . Smoking
- . Previous radioactive iodide scanning or other imaging techniques with administration of iodide containing contrast fluids within 6 months
- . Use of supplements that contain large quantities of iodide
- . Structural alcohol intake > 3 glasses/day
- . Subjects who have taken part in any drug trial within 3 months prior start of this study.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	09-05-2016
Aantal proefpersonen:	17
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies	
Datum:	10-05-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 43413
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5700
NTR-old	NTR5853
CCMO	NL56309.091.16
OMON	NL-OMON43413

Resultaten