The relation between free serotonin in plasma, serotonin in platelets, and the type of serotonin transporter in carcinoid tumor patients, patients using SSRI, and healthy controls.

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1. The concentrations serotonin and dopamine are different between carcinoid tumor patients, patients using SSRI, and healthy controls; 2. The concentration free serotonin in plasma, and the ratio free serotonin/serotonin in platelets is determined…

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24450

Bron
Nationaal Trial Register

Verkorte titel
SERT

Aandoening

In English: carcinoid tumor, SSRI, selective serotonin reuptake inhibitor, serotonin, plasma, platelets, serotonin transporter.
Nederlands: carcinoïd tumor, SSRI, selectieve serotonine heropname remmers, serotonine, plasma, bloedplaatjes, serotonine transporter

Ondersteuning

Primaire sponsor: University Medical Center Groningen
Overige ondersteuning: University Medical Center Groningen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Analyzing whether there is a difference in the concentration dopamine and serotonin in the plasma and platelets of carcinoid tumor patients, patients using SSRI, and healthy controls.

Toelichting onderzoek

Achtergrond van het onderzoek

Introduction:

Serotonin is a neurotransmitter that is responsible for several physiological processes in the body, e.g. muscle contraction, blood pressure regulation, and peripheral en central neurotransmission. The serotonin transporter (SERT) is the most important regulator of the concentration free serotonin in the plasma, because it transports serotonin from the plasma into platelets, enterochromaffin cells, and neurons, where serotonin is stored and metabolized. Serotonin also has a role in depression. Part of the patients with a carcinoid tumor produce surplus of serotonin. To investigate the correlation between free plasma serotonin and its effect on the cardiovascular system, gastrointestinal tracts, and the lungs, free serotonin in plasma has to be determined. Until now, no analytic method was available to reliably determine this concentration.

Aim:

1. To analyze the concentration dopamine and serotonin in the plasma and platelets of carcinoid tumor patients, patients using SSRI, and healthy controls;

2. To analyze the influence of the genotype of the serotonin transporter on the concentration free serotonin in plasma, and the ratio free serotonin/serotonin in platelets.

Methods:

This is a cross-sectional study. Of 30 carcinoid tumor patients, 70 patients using SSRI, and 5 healthy controls 24mL EDTA blood will be obtained. Dopamine, and serotonin in plasma and platelets, and the genotype of the serotonin transporter will be determined.

Doel van het onderzoek

1. The concentrations serotonin and dopamine are different between carcinoid tumor patients, patients using SSRI, and healthy controls;

2. The concentration free serotonin in plasma, and the ratio free serotonin/serotonin in platelets is determined by the genotype of the serotonin transporter.

Onderzoeksopzet

This is a cross-sectional study: At one time point 24mL EDTA blood will be obtained.

Onderzoeksproduct en/of interventie

No intervention: At one time point 24mL EDTA blood will be obtained from the patient.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Ethics:

1. Approval of the METC UMCG;

2. Written informed consent.

Participants:

1. Healthy men or women;

2. Patients with a metastasized carcinoid tumor, that produces serotonin;

3. Patients with a depression or anxiety disorder, which use selective serotonin reuptake inhibitors:

A. The diagnosis is based on the judgement of the patient's current doctor;

B. The depression/anxiety disorder can be present or in remission;

C. Treatment with SSRI should be at least 6 weeks, and the dose should be suitable (citalopram 20mg; escitalopram 10mg; fluvoxamine 100mg; fluoxetine 20mg; paroxetine 20mg; sertraline 50mg).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. The use of medication that interferes with the serotonin metabolism or serotonin reuptake (exception: use of SSRI in patients with depression/anxiety disorder), for example aspirin, psychofarmaca (other than SSRI (TCA, MAO-inhibitors, mirtazapine, bupropion, venlafaxine, duloxetine), anxiolytics, antipsychotics, and anticonvulsants;

2. Drug abuse (8 weeks prior to inclusion);

3. Alcohol abuse (8 weeks prior to inclusion: females: >14 glasses a week, males: >21 glasses a week);

4. Consumption of walnuts or bananas 48 hours prior to obtaining of blood sample.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-02-2011
Aantal proefpersonen:	105
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	10-04-2012
Soort:	Eerste indiening

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	ID
NTR-new	NL3241
NTR-old	NTR3393
Ander register	METC UMCG : 2009/171
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A