The relation between free serotonin in plasma, serotonin in trombocytes and the genotype of the serotonin transporter in carcinoid patients, patients on selective serotonin reuptake inhibitors and healthy controls.

Published: 05-11-2009
Last updated: 06-05-2024

To determine the influence of the serotonin transporter activity on the plasma free serotonin and dopamine amount and the stored amount (in trombocytes) in three different populations (healthy controls, carcinoid patients and patients on medication...

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

Summary

ID

NL-OMON35209

Source
ToetsingOnline

Brief title
Relation between serotonin levels and genotype of serotonin transporters

Condition

- Other condition
- Mood disorders and disturbances NEC

Synonym
Carcinoid tumors, depression, mood disorder, serotonin producing tumors

Health condition

carcinoid tumoren

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Genotype, Serotonin, Serotonin transporter

Outcome measures

Primary outcome

Free and stored serotonin and dopamine is measured in plasma and trombocytes,

respectively. DNA is isolated form whole blood for genotyping of the serotonine

transporter.

Secondary outcome

na

Study description

Background summary

Serotonin (5-hydroxytryptamine), a neurotransmitter, is involved in many physiological processes in the body, such as muscle contraction, regulation of blood pressure, and neurotransmission in the periphery abd the central nervous system. The serotonin transporter (SERT) is the most important regulator of the biologically active free serotonin in the circulatio. It takes care of extracellulair free serotonin transport over the celmembrane into the trombocytes, neurons and enterochromaffin cells, where storage and metabolism take place. Pathophysiologically, serotonine plays a role in a.o. depression. Excessive periphere serotonine synthesis, storage, excretion and metabolism is the most important characteristic of carcinoid patients.

To investigate the correlation between plasma free serotonin and its actions on the cardiovasculair system, the gastro-intestinal and the respirative tract, the free fraction need to be measured. So far, no methods or machinery were available to analyze this fraction in a relaibale way, and therefore only the platelet stored serotonin concentrations (present in higher amoubts) were measured.

Study objective

To determine the influence of the serotonin transporter activity on the plasma free serotonin and dopamine amount and the stored amount (in trombocytes) in three different populations (healthy controls, carcinoid patients and patients on medication altering the serotonin availability (SSRIs in depressive patients and patients with an anxiety disorder).

Primary research question
Is there a difference in the amounts of free serotonin and dopamine and trombocytes-stored serotonin and dopamine between healthy controls, serotonin-producing carcinoid patients and patients on medication altering the serotonin availability (SSRIs in depressive patients and patients with an anxiety disorder)?

Secundary research question
Is the serotonin transporter activity responsible for the amount of free serotonin in plasma and the stored amount in trombocytes and is there a difference between the three groups?

Study design

Carcinoid patients (30), patients on SSRI-medication (70) and healthy controls (5) participate in the study. Blood is collected for the analysis of plasma free serotonine and dopamine, in trombocytes stored serotonin and dopamine and genotyping of the serotonin transporter present on the trombocytes.
There are no risks attached to participation. Venapunction is the only burden.
To quantify serotonin and dopamine isotope-dilution mass spectrometry is used.
Real-time polymerase chain reaction is applied
to genotype the sertonine transporter.

Study burden and risks

Blood will be sampled once by venapuncture (21 mL). Medical risks due to participation in the study is minimal.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
9700 RB Groningen
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
9700 RB Groningen
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Healthy volunteers
Patients with serotonin producing carcinoid tumors
Patients on SSRIs for the treatment of depression

Exclusion criteria

Subjects on mediation that influences serotonin-metabolisme, such as aspirine, antidepressive medication, MAO-inhibitors or is involved in serotonin reuptake, with the exception of SSRIs in the SSRI group.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2011
Enrollment:	105
Type:	Actual

Ethics review

Approved WMO Date:	05-11-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	04-05-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	25-04-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
CCMO	NL28578.042.09