Gene polymorphisms and susceptibility to psychopathology in patients with metastatic carcinoid disease

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In this study will be examined whether the polymorphisms of above mentioned genes are related to the occurrence and extent of psychiatric symptoms in patients suffering from carcinoid tumors. Since serotonin metabolism depends also on the tumor…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Endocrine neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON30789

Source
ToetsingOnline

Brief title
Gene polymorphisms and psychopathology

Condition

- Endocrine neoplasms malignant and unspecified
- Psychiatric and behavioural symptoms NEC

Synonym
carcinoid tumor

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: carcinoid, gene polymorphism, psychopathology, tryptophan

Outcome measures

Primary outcome

- Biochemical data serotonin metabolism

- Gene polymorphisms

- Outcome questionnaires

Primary outcome: the relationship between certain gene polymorphisms and

psychiatric symptomatology.

Secondary outcome

no

Study description

Background summary

Carcinoïd tumours are slowly growing malignant neuro-endocrine tumours secreting various factors, of which serotonin is the most prominent one. The production of serotonin in the carcinoid can increase so dramatically, that a major fraction of whole body tryptophan is peripherally converted to serotonin. Serotonin is not able to pass the blood brain barrier, thus the cerebral synthesis of serotonin is highly dependent on the availability of tryptophan in the blood circulation. Consequently, carcinoid tumor can lead to cerebral depletion of serotonin. Previously was found that tryptophan depletion can lead to increased irritability and aggression in humans with a carcinoid tumor and animals. The relationship between serotonin and the presence of symptoms is not always consistent and not all patients develop these symptoms. Apparently, some individuals are more vulnerable for the consequences of tryptophan depletion than others. This could be because of different gene polymorphisms in genes that code for serotonin metabolism and/or noradrenergic function. Recently a number of gene polymorphisms that affect serotonergic and noradrenergic activity have been described. Of interest are polymorfisms of monoamine

oxidase-A, the serorotonin transporter, tryptophan hydroxylase and catecholamine-O-methyltransferase.

Study objective

In this study will be examined whether the polymorphisms of above mentioned genes are related to the occurrence and extent of psychiatric symptoms in patients suffering from carcinoid tumors. Since serotonin metabolism depends also on the tumor activity, the relationship clinical symptoms and biochemical parameters will be studied as well.

Study design

The design of this study is prospective. Polymorphism for 5-HTT, MOA-A and COMT will bedetermined.
Psychopathology will be assessed by using the Symptom Checklist-90 (SCL-90) and the Buss-Durkee Hostility Inventory (BDHI) three self-rating scales, in the home situation. The SCL-90 is used to assess general mental health, because it evaluates a broad range of psychological problems and symptoms of psychopathology. Russo et. al. found that the main problems that occur in carcinoid patients are irritability and disturbed impulse control. We*ll use the BIS and BDHI to assess these symptoms. The BHDI are among the oldest and widely used self-administered impulsivity tests. Total time investment for patients and their partners will be about 60 minutes.

Study burden and risks

Questionnaires (appr. 60 minutes)
Venapuncture

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients with a proven carcinoïd syndrome, in who plasma tryptophan and urinary 5-HIAA levels are recently determined

Exclusion criteria

Patients who, after being informed about the study, are not willing to participate.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-04-2007
Enrollment:	150

Type:	Actual

Ethics review

Approved WMO	
Application type:	First submission
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	NL11819.042.06