

Psychiatric and cognitive function in patients with Neuroendocrine tumours with carcinoid syndrome.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON45631

Source

ToetsingOnline

Brief title

Psychiatric and cognitive function in patients with NET.

Condition

- Other condition
- Mood disorders and disturbances NEC

Synonym

cognitive impairment, depression

Health condition

cognitieve stoornissen

Research involving

Human

Sponsors and support

Primary sponsor: Nederlands Kanker Instituut

Source(s) of monetary or material Support: geen

Intervention

Keyword: carcinoid syndrome, cognitive function, neuroendocrine tumour, psychiatric function

Outcome measures

Primary outcome

To assess the severity of cognitive dysfunction and depressive symptoms in ileal NET patients and to relate this to peripheral 5-HT production.

Secondary outcome

- To assess the prevalence of formal psychiatric diagnoses (depressive disorder, anxiety disorder) in patients with metastatic ileal NET and relate this to peripheral 5-HT production
- To assess the severity of irritability and anger in patients with metastatic ileal NET and to relate this to peripheral 5-HT production.
- To identify subgroups of patients with metastatic ileal NET that are more vulnerable for depressive symptoms (e.g. with a (family) history of depression or a polymorphism in serotonin transporter genes).
- To assess the prevalence of cognitive problems on specific domains in patients with metastatic ileal NET and relate this to peripheral 5-HT production.
- To assess the emotional bias in NET patients and to relate this to 5-HT production, depressive symptoms and irritability
- To assess the association between psychiatric symptoms and cognitive

impairment and peripheral 5-HT production.

- To assess the quality of life of the patients and to relate this to peripheral 5-HT

Study description

Background summary

Patients with neuroendocrine tumours (NET) report cognitive problems and psychiatric symptoms such as depressed mood, anxiety and irritability. These problems and symptoms are thought to be related to cerebral shortage of the serotonin precursor tryptophan, that is depleted by peripheral overproduction by the tumour. The clinical manifestation of serotonin (5-HT) overproduction (diarrhoea, flushes and wheezing) is known as carcinoid syndrome (CS) which can be present in metastasized (M1) ileal NET tumours. The exact role of 5-HT metabolism in psychopathology, however, is still unclear.

Study objective

This study aims to assess impairments in cognition and psychiatric function in ileal NET patients and relate this to 5-HT metabolism, by investigating the relation between psychiatric and cognitive function of ileal M1 NET patients to peripheral 5-HT production.

The study has two main objectives: First, to study the relation between cognitive function and peripheral 5-HT production. Second, to study the relation between the severity of depressive symptoms and peripheral 5-HT production.

Secondary objectives are to assess psychiatric diagnoses within the patient group and relate them to 5-HT production and to assess the severity of irritability and its relation to 5-HT production.

Study design

observational study

Study burden and risks

The risks of this study are negligible. The burden of the study is one site visit to the hospital. 2 extra blood samples will be taken during the blood sample withdrawal as part of the standard care. 24 hour urine sample is extra

and will be done by the patient during the 24 hours prior to hospital visit. During the hospital visit questionnaires, neuropsychological testing and psychiatric evaluation will take place. The estimated time for the evaluation is 2 * hours.

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 ileal NET with metastatic disease, diagnosed between 2012 and 2017
- Signed informed consent

Exclusion criteria

- No sufficient understanding of the Dutch language.
- A previous cerebro vascular accident (assessed through review of the chart and checked with the patient)
- Severe cognitive problems such as a dementia.
- Delirium in the past 3 months
- Use of 5-HT modulating medication, such as SSRIs or SNRIs, or tryptophan
- Current chemotherapy, or chemotherapy in the past 5 years
- Previous malignancy in the past 5 years, except for adequately treated basal cell carcinoma of the skin.
- Life expectancy shorter than 3 months
- Patients with a primary psychotic disorder (schizophrenia)

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 10-07-2017

Enrollment: 85

Type: Actual

Ethics review

Approved WMO

Date: 17-05-2017

Application type: First submission

Review commission: METC NedMec

Approved WMO

Date: 21-03-2018
Application type: Amendment
Review commission: METC NedMec

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	NL61238.031.17