Exploring the metabolic profile of neuroendocrine tumors

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

Summary

ID

NL-OMON43011

Source
ToetsingOnline

Brief title
Indol

Condition

- Endocrine neoplasms malignant and unspecified

Synonym
kanker, neuroendocrine tumor

Research involving
Human

Sponsors and support

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

Intervention

Keyword: catecholamines, indol profile, LC-MS/MS, neuroendocrine tumors

Outcome measures

Primary outcome

In this exploratory study we will measure the indol profile in patients with a foregut NET, mid- and hindgut NET, and healthy volunteers at the time of diagnosis and during follow up and treatment in plasma and urine.

Secondary outcome

In addition, levels of catecholamines and metabolites in these three groups will be determined.

Study description

Background summary

Neuro-endocrine neoplasms are a diverse group of tumors which encompasses heterogeneous clinical courses. Different NETs are characterized by differences in the synthesis, storage and release of biogenic amines and their metabolites, e.g. indoles, catecholamines and their metabolites. Clinical course, prognosis, and treatment are based, among others, on the origin of the primary tumor. Up to now it was only possible to measure metabolic output of NETs by serotonin in platelets and 5-HIAA in urine. Due to technical improvements we can now measure the complete metabolic pathway of serotonin in plasma and urine, which comprises tryptophan, 5-hydroxytryptophan, serotonin and 5-HIAA, the indol profile. Furthermore, levels of catecholamines and metabolites can now be analyzed in the same sample. This metabolic profiling could potentially lead to improved diagnosis and characterization of NET patients and possibly contribute to subsequent treatment consequences.
Therefore, we want to perform an exploratory study to measure the indol profile, catecholamines and metabolites in patients with NETs of different origin (foregut, midgut and hindgut) and assess differentiation of their metabolic profile.

Study objective

The aim of this study is to explore the added value of the indol profile in comparison to serotonin in platelets and 5-HIAA in urine for diagnosis and potentially management of neuroendocrine tumors including gastrinomas, pNETs and brochopulmonary NETs.

Study design

This is an observational and exploratory study. Participants will be asked for a blood collection and a 24- hour collection of urine. The indol profile and levels of catecholamine and metabolites in PRP, as well as in 24- hour collection of urine will be measured with LC-MS/MS and analyzed.

Study burden and risks

Patients with midgut NET already have blood collections and urinary collection as part of evaluation of their treatment. Only for patients with foregut NETs and some of the healthy volunteers one extra blood collection with a vena puncture will be taken. This gives a small risk of bruising. Furthermore a 24-hours collection of urine will be collected with a prescription to their diet 48 hours before the collection. This could give some distress.

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

Inclusion criteria for all subjects:
- written informed consent
- age above 18 years
Inclusion criteria for patients with a NET: (one of these)
- histologically proven NET, with or without treatment for the NET
- a diagnosis made by a dedicated NET specialist based on a combination of physical symptoms and signs, imaging and laboratory values.
Inclusion criteria for healthy subjects:
- Matching in age (plus or minus 3 years) and sex with one of the included NET patients.
Data of healthy subjects could also be used from the SERT-study, if the subject meets the criteria mentioned above.

Exclusion criteria

Exclusion criteria for all subjects:
- Use of drugs or food supplements that interact with the serotonin-metabolism; all serotonin re-uptake inhibitors, psychotrophic drugs, (other antidepressants; tricyclic antidepressants, MAO-inhibitors, mirtazapin, bupropion, venlafaxin, duloxetin, anxiolytic, antipsychotic and anticonvulsive drugs).
- Drug abuse in the last 8 weeks.
- Use of >= 14 alcoholic consumptions a week for women.
- Use of >= 21 alcoholic consumptions a week for men.
Exclusion criteria for healthy subjects:
- Having a neuroendocrine tumor or neuroendocrine carcinoma from any grade and location in present or in history.
- Having a malignancy.
- Having an auto-immune disease.
- Having an infection.
- Having renal impairment.
- Use of interferon.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-10-2016
Enrollment:	210
Type:	Actual

Ethics review

Approved WMO Date:	23-09-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	20-12-2017
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
Other	clinical trials volgt
CCMO	NL58164.042.16