# Towards optimal personalized diet and vitamin supplementation in patients with a neuroendocrine tumor.

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Vitamin related disorders |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON43061

**Source**
ToetsingOnline

**Brief title**
DIVIT

### Condition

- Vitamin related disorders
- Endocrine neoplasms malignant and unspecified

**Synonym**
neuroendocrine tumor, vitamin

**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:** diet, neuroendocrine tumor, vitamin

## Outcome measures

### Primary outcome

Primary endpoint is the change in the proportion of patients with normal vitamin values measured with quantitative analysis of blood and urine.

### Secondary outcome

Secondary endpoint will be the nutrition state (Patient-Generated Subjective Global Assessment PG/SGA), distress measured by the distress thermometer and change in quality of life as determined by the NET-specific EORTC QLQ-GINET21 and the cancer-specific EORTC QLQ-C30, and the difference of self-reported healthy eating pattern.

Furthermore a semi qualitative interview will be performed at t=18 to investigate the satisfaction of patients about the intervention.

# Study description

### Background summary

Patients with neuroendocrine tumors (NET) have a rare, slowly progressing disease, which can produce bioactive amines. They may undergo many treatments regimens such as surgery followed by systemic treatments with somatostatin analogues. The tumor, the produced bioactive amines and these treatment regimens can result in increased diarrhea and loss of critical food components in the stools such as fat and fat-soluble vitamins. Which can lead to vitamin deficiencies leading to several symptoms and complaints. In addition patients can suffer from tumor related serotonin production leading to profuse diarrhea and shortage of tryptophan. Tryptophan is a precursor of niacin (vitamin B3) which is critical for normal cellular metabolism. Deficiencies of tryptophan niacin can lead to symptoms including pellagra.
Strikingly little is known about how to supply for these vitamin deficits and

how NET patients can prevent deficiencies by diet interventions.
Patients with NET are faced with a serious chronic disease. This makes this patient group extremely motivated to be involved in their treatment and to *self-manage* their disease as much as possible.

## Study objective

This study aims to investigate if the proportion of NET patients with normal vitamin values can be increased, with vitamin suppletion and a personalized diet, measured with quantitative analysis of blood and urine. Secondary aims are an improvement in nutrition state Patient-Generated Subjective Global Assessment (PG/SGA), a decrease in distress on the distress thermometer, improvement in quality of life as determined by the NET-specific EORTC QLQ-GINET21 and the cancer-specific EORTC QLQ-C30. In additionFurthermore the the self-reported healthy eating pattern will be evaluated and the satisfaction of patients about the intervention will be assessed by a semi-qualitative interview.

## Study design

This is a single center 18-week open-label, non-comparative, single-arm, intervention study. After inclusion and the first measurements, adult patients with metastasized or iresectable NET will continue with four weeks of standard treatment. After these four weeks participants with vitamin values below normal will get vitamin suppletion for each deficient vitamin and all participants will get the dietary intervention during 14 weeks. Effects of the intervention will be evaluated by quantitative analysis of blood and urine and questionnaires. The measurements, including; baseline characteristics, quantitative analysis of blood and urine and questionnaires will be performed at baseline (t=0), after 4 weeks (t=4) and after 18 weeks at end of study (t=18). Furthermore at t=18 a semi-qualitative interview will be performed.

## Intervention

In the first four weeks after inclusion patients will get standard care. The measurements, including; baseline characteristics, quantitative analysis of blood and urine and questionnaires will be performed at baseline (t=0), after four weeks (t=4), and after 18 weeks (t=18). Furthermore, at t=18 a semi qualitative interview will be performed.
The first four weeks will be used to observe the variability of the vitamin values during standard treatment. If patients have deficient vitamins at baseline t=0 or Tt=4 weeks, we will start with vitamin suppletion. During the intervention period, patients will in addition to standard treatment be counseled by a dietician for 14 weeks. A personalized diet advice for each NET patient will be based on the individual situation which includes the current food intake of the patient, gastrointestinal complaints, the location of the

tumor, additional treatments like previous surgery and measured vitamin and tryptophan levels.
All diets are based on the Dutch guidelines of the *voedingscentrum*. The personalized diet advice provides patients insight in how they could adjust their diet to experience fewer symptoms. Advices could consist of eating more proteins, eating more soluble fibers or, for patients with pancreas insufficiency, to motivate patients to eat fatty products in combination with pancreas enzyme capsules. A diet with frequent small meals and with complex carbohydrates, will be prescribed for patients with an insulinoma. Dietician consults will be conducted by 1 out-patient visit and 3 follow up contacts in week 5, 10 and 15 by telephone.

**Study burden and risks**

Most patients with a NET can live for many years with their disease. Disease and treatment related vitamin deficiency, impaired nutrition state, distress and an impaired quality of life can be an additional burden for these patients. With this study we aim to detect that adequate vitamin suppletion and additional a personalized diet will result in an increase in the proportion of patients with normal vitamin values and an improvement in their nutrition state, distress, quality of life and satisfaction in the intervention.

# 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

* Adult patients aged * 18 years
* NET-patients with serotonine producing or non-serotonin producing tumors, with gastro-intestinal, pancreatic, bronchopulmonary or unknown primary tumor site and with metastasized or irresectable disease.
* Ability to comprehend Dutch (both reading and writing).
* Written informed consent provided.
* Use of somatostatin analogue for > 6 months.

## Exclusion criteria

* Estimated life expectancy less than 6 months.
* Patients who have a history of another primary malignancy, except for radical and adequately treated malignancies from which the patient has been disease free for * 1 year.
* Major abdominal surgery during study period.
* Patients already participated in the DIVIT-pilot study
* Known hypersensitivity of (components of) somatostatin analogue

# Study design

## Design

**Study type:** Interventional

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| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Treatment |

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 15-12-2016 |

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| Enrollment: | 53 |
| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 30-11-2016 |
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Groningen (Groningen) |
| Approved WMO Date: | 22-01-2018 |
| 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 |
|---|---|
| ClinicalTrials.gov | NCTnummervolgt |
| CCMO | NL58625.042.16 |