Towards optimal personalized diet and vitamin supplementation in patients with a neuroendocrine tumor; a pilot study

Published: 21-04-2015
Last updated: 13-04-2024

This study aims to investigate if optimal personalized consultation by a dietician for a healthy diet focused on food which contains sufficient vitamins and minerals improves gastrointestinal symptoms as determined by an improved score in the...

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

Summary

ID

NL-OMON41959

Source
ToetsingOnline

Brief title
DIVIT-pilot

Condition

- Vitamin related disorders
- Endocrine neoplasms malignant and unspecified

Synonym
neuroendocrine tumor/distress, vitamine

Research involving
Human

Sponsors and support

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

Intervention

Keyword: diet, neuroendocrine tumor, tryptophane, vitamin

Outcome measures

Primary outcome

Primary endpoint is the difference in mean gastro-intestinal symptoms score of the EORTC QLQ-GINET21.

Secondary outcome

Secondary endpoint will be distress measured by the distress thermometer and change in quality of life as determined by the cancer-specific EORTC QLQ-C30, and the other constructs of the EORTC QLQ-GINET21, empowerment (subscales of the Construct Empowering Outcomes (CEO) questionnaire) at end of study, the difference in nutrition state (Patient-Generated Subjective Global Assessment PG/SGA) and normalization of vitamins and tryptophan levels at end of study measured with quantitative analysis of blood and urine.

Study description

Background summary

Patients with neuroendocrine tumors (NET) have a rare, slowly progressing disease. Therefore they undergo many treatments such as surgery followed by long-lasting systemic treatments with somatostatin analogues. These procedures can each result in increased diarrhea and loss of critical food components in the stools such as fat. This can lead amongst others, to major loss of fat-soluble vitamins. Those patients who in addition have an ongoing serotonin production may experience shortage in the circulating essential amino acid tryptophan. Serotonin is derived from the essential amino acid tryptophan. Tryptophan is a precursor of niacin (vitamin B3) which is critical for normal cellular metabolism. In case of high serotonin production in neuroendocrine tumor patients tryptophan and/or niacin can be deficient leading to symptoms including pellagra. Suppletion of tryptophan might facilitate serotonin

production and therefore, is undesirable in patients with serotonin producing neuroendocrine tumors.
Strikingly little is known about how NET patients should be best supported for the deficits they develop during their long-lasting disease. Also the precise effect of diet advices for diarrhea and fat-soluble vitamins and vitamin B3, in this patient group is unknown.
Patients with NET are faced with a serious chronic disease. This makes this patients 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 optimal personalized consultation by a dietician for a healthy diet focused on food which contains sufficient vitamins and minerals improves gastrointestinal symptoms as determined by an improved score in the gastrointestinal symptoms of the NET specific EORTC QLQ-GINET21 at end of study. Secondary aims are decrease in distress on the distress thermometer, improvement in quality of life as determined by the cancer-specific EORTC QLQ-C30, and the other constructs of the EORTC QLQ-GINET21, empowerment (subscales of the Construct Empowering Outcomes questionnaire) at end of study, an improvement in nutrition state (Patient-Generated Subjective Global Assessment PG/SGA) and normalization of vitamins and tryptophan levels at end of study measured with quantitative analysis of blood and urine.

Study design

This is a single center 18-week open-label, non-comparative, single-arm, experimental pilot study. In this pilot study we want to examine the effect sizes of the gastrointestinal symptoms of the NET specific EORTC QLQ-GINET21 of the patients after the dietary intervention.
. Four weeks after inclusion adult patients with metastasized NET and chronic use (>6 months) of a somatostatin analogue will start with the dietary intervention. Effects of the intervention will be evaluated by questionnaires and vitamin values in blood and urine.
Patients fill out these questionnaires at baseline, after four weeks, and after 18 weeks. Furthermore at baseline, after four weeks and then after 18 weeks vitamin values in blood and urine will be measured and at baseline.

Intervention

In the first four weeks after inclusion patients will get standard care.
Patients fill out the questionnaires at baseline, after four weeks, and after 18 weeks. The first month will be used to observe the variability of the scores of the gastrointestinal symptoms of the QLQ-GINET21. Four weeks after inclusion patients will be counseled by a dietician for 14 weeks. A tailored diet advice

for each NET patient will be based on the individual situation which includes gastrointestinal complaints, the location of the tumor, additional treatments like previous surgery and measured vitamine and tryptophan levels.
All diets are based on the Dutch guidelines of the *voedingscentrum*. The tailored 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. If medically indicated patients will be supplied with supplements.
Dietician consults will be conducted by 1 out-patient visit and 3 follow up contacts (by visit/telephone or video consultation system).

Study burden and risks

Most patients with a NET can live for many years with their disease. Disease and treatment related diarrhea and vitamin deficiency can be an additional burden for these patients. With this study we aim to detect that additional dietician consults and adequate vitamin suppletion will result in a difference in gastro-intestinal symptoms and distress and, in addition to adequate vitamin and tryptophan levels.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713 GZ
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713 GZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Adult NET patients (aged >= 18 years of age), with serotonine producing or non-serotonin producing tumors, with any tumor site and disease stage.
• Use of somatostatin analogue for > 6 months.
• Ability to comprehend Dutch (both reading and writing).
• Written informed consent provided.

Exclusion criteria

• Estimated life expectancy less than 3 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 >= 3 years. •
• Major abdominal surgery during study period.
• Known hypersensitivity of (components of) somatostatin analogue.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2015
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO Date:	21-04-2015
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
ClinicalTrials.gov	NCTnummervolgt
CCMO	NL51141.042.15