VITAMin Insufficiency in esophagogastric Neoplasms

Published: 06-10-2021 Last updated: 18-07-2024

To identify which micronutrient deficiencies are most common after surgery for esophagogastric neoplasms and to observe the effect of supplementation.

Ethical review Approved WMO

Status Recruitment stopped

Health condition type Gastrointestinal motility and defaecation conditions

Study type Interventional

Summary

ID

NL-OMON50515

Source

ToetsingOnline

Brief title

VITAMIN

Condition

- Gastrointestinal motility and defaecation conditions
- Gastrointestinal therapeutic procedures

Synonym

vitamin deficiency

Research involving

Human

Sponsors and support

Primary sponsor: Zuyderland Medisch Centrum

Source(s) of monetary or material Support: Gikavi Supplements BV

Intervention

Keyword: VITAMIN

Outcome measures

Primary outcome

The primary endpoint is any deficiency (yes/no) defined as any of the below mentioned vitamins, minerals and proteins.

The main study parameters are measurements of nutrient blood levels measured at baseline.

and after 6, 12, 24 months supplementation to identify and resolve deficiencies, including:

- Haemoglobin, haematocrit, MCV
- Vitamins: B1, B6, B11, B12, A, D, E K
- Methylmalonic acid when serum vitamin B12 < 350 pmol/L
- Minerals: serum iron, calcium, zinc, magnesium
- Parathyroid hormone
- Proteins: ferritin/transferrin, Transferrin saturation percentage (TS%)
- Creatinine
- Phosphate

Secondary outcome

The secondary endpoints are:

- -Albumin, total protein
- -C-reactive protein

- -Incidence of micronutrient deficiency post oesophageal or (sub-)total gastrectomy at baseline
- -Occurrence of exocrine pancreatic insufficieny (EPI)
- -Occurrence of the following symptoms: diarrhoea, steatorrhea, bloating which are all associated with EPI
- -QoL measured with questionnaires at baseline and after 6 months, 12 months and
- 24 months of supplementation
- -Vitality of patient at baseline and after 6 months, 12 months and 24 months of supplementation

Study description

Background summary

Oesophageal cancer (EC) and gastric cancer (GC) are among the top ten cancers worldwide, with rapidly increasing incidence and mortality (1, 2). Because of the invasion of the digestive tract, both diseases have a major impact on the nutritional status of patients and their quality of life (QoL). In the part of the population with oesophageal or stomach cancer that is treated with a curative intent, surgery is the main and most effective treatment for both diseases. However, anatomical changes after esophagogastric surgery may affect nutritional intake and absorption in the gastrointestinal tract in several ways.

Due to the oncologic surgical resection of the oesophagus and/or a significant part of the stomach the intake and uptake of nutrients is often decreased, causing malnutrition. Malnutrition is reported in 50-80% of patients with GC or EC and is associated with a high incidence of morbidity, lower survival rates and poorer treatment outcomes. For this reason, nutritional status of these patients has been receiving more attention in clinical research.

Study objective

To identify which micronutrient deficiencies are most common after surgery for esophagogastric neoplasms and to observe the effect of supplementation.

Study design

multi centre intervention study.

Intervention

Two tailormade supplements for patients; one for that underwent esophagectomy and one for (sub-)total gastrectomy.

Study burden and risks

In this study, no health-related risks are present for participants due to the administration of supplementation that is already used as in clinical practice.

Contacts

Public

Zuyderland Medisch Centrum

Dr. H. van der Hoffplein 1 Sittard-Geleen 6162 BG NI

Scientific

Zuyderland Medisch Centrum

Dr. H. van der Hoffplein 1 Sittard-Geleen 6162 BG NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

Patients >=18 years of age who underwent an esophagectomy or (sub-)total gastrectomy for malignancy with no signs of postoperative recurrence of disease.

Exclusion criteria

- Patients that underwent a wedge resection of the stomach
- Malignant disease recurrence
- Metastases
- Patients that are not capable to take supplementation due to altered mental status or swallow difficulties
- No signed informed consent
- Patients who are receiving chemotherapy
- Patients with high vitamin status at baseline, except for vitamin b12

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 17-12-2021

Enrollment: 248

Type: Actual

Ethics review

Approved WMO

Date: 06-10-2021

Application type: First submission

Review commission: METC Z: Zuyderland-Zuyd (Heerlen)

Approved WMO

Date: 12-07-2022

Application type: Amendment

Review commission: METC Z: Zuyderland-Zuyd (Heerlen)

Approved WMO

Date: 01-08-2022

Application type: Amendment

Review commission: METC Z: Zuyderland-Zuyd (Heerlen)

Approved WMO

Date: 24-04-2023

Application type: Amendment

Review commission: METC Z: Zuyderland-Zuyd (Heerlen)

Approved WMO

Date: 10-06-2024

Application type: Amendment

Review commission: METC Z: Zuyderland-Zuyd (Heerlen)

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 NCT05281380 CCMO NL78919.096.21