VITAMin Insufficiency in esophagogastric Neoplasms

Published: 06-10-2021
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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

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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 >=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