VITAMin Insufficiency in esophagogastric Neoplasms or the VITAMIN study

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25636

Source
Nationaal Trial Register

Brief title
VITAMIN

Health condition

Esophageal cancer and gastric cancer

Sponsors and support

Primary sponsor: GIKAVI
Source(s) of monetary or material Support: GIKAVI

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

• The incidence of exocrine pancreatic insufficiency
• To prevent consequences of micronutrient deficiencies as iron-deficiency anemia, rickets, folic acid anemia, disturbed vision, mental declination.
• To measure quality of life post-operative
• To measure quality of life regarding vitality post supplementation.

Study description

Background summary

Rationale: Esophageal cancer and gastric cancer are among the top ten most common cancers worldwide. Both diseases have major impact on the nutritional status of patients and their quality of life. Studies investigating post-operative nutritional status are limited and postoperative identification and treatment of micro- and macronutritional deficiencies are currently lacking in (inter-)national guidelines.

Objective: To identify and target vitamin deficiencies after surgery for esophagogastric neoplasms.

Study design: Single centre intervention study.

Study population: Patients aged 18 years and older that underwent esophagectomy or (sub-)total gastrectomy for esophagogastric neoplasms.
Intervention (if applicable): Two tailormade supplements for patients; one for that underwent esophagectomy and one for (sub-)total gastrectomy.

Main study parameters/endpoints: Baseline micronutrient deficiency measurements and after 6, 12, 24 months supplementation,.

Secondary study parameters/ endpoints: Occurrence of exocrine pancreatic insufficiency (n,%), occurrence of diarrhoea (n,%), steatorrhea (n,%), bloating (n,%), time between surgery and start of supplementation (mean in months), quality of life experienced (questionnaires) at baseline and after 6, 12, 24 months supplementation.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: 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.

Study objective

After surgery for esophageal cancer and gastric cancer micronutrient deficiencies are common and standard suppletion to prevent deficiencies should be performed.

Study design

Baseline micronutrient deficiency measurements and after 6, 12, 24 months supplementation.

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

A potential subject who meets any of the following criteria will be included for participation in this study:
- Patients ≥18 years of age who underwent an esophagectomy or (sub)total gastrectomy for malignancy with no signs of postoperative recurrence of disease.
- Written voluntary informed consent (IC).

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- 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

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2021
Enrollment:	248
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	18-10-2021
Application type:	First submission

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
NTR-new	NL9787
Other	METC Zuyderland : METCZ20210146

Study results