VITAMin Insufficiency in esophagogastric Neoplasms or the VITAMIN study

Gepubliceerd: 18-10-2021 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25636

Bron
Nationaal Trial Register

Verkorte titel
VITAMIN

Aandoening

Esophageal cancer and gastric cancer

Ondersteuning

Primaire sponsor: GIKAVI
Overige ondersteuning: GIKAVI

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-11-2021
Aantal proefpersonen:	248
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	18-10-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9787
Ander register	METC Zuyderland : METCZ20210146

Resultaten