

Vitamin B12 deficiency after esophagectomy with gastric tube reconstruction.

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Objective of this study is to determine the prevalence of vitamin B12 deficiency among patients who underwent esophagectomy with GTR. The following specific research questions have been defined:- What is the prevalence of vitamin B12 deficiency in...

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

Summary

ID

NL-OMON36384

Source

ToetsingOnline

Brief title

VIDEO-study

Condition

- Vitamin related disorders
- Gastrointestinal neoplasms malignant and unspecified

Synonym

cobalamine deficiency, vitamin B12 shortage

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Deficiency, Esophagectomy, Vitamin B12

Outcome measures

Primary outcome

Primary outcome of the study is the presence of vitamin B12 deficiency, prior or after esophagectomy with GTR.

Secondary outcome

- The time of onset of a vitamin B12 deficiency during follow-up.
- Vitamin B12 intake, according to standardized questionnaires

Study description

Background summary

The absorption of vitamin B12 in the human body is a phased process. Extracting B12 out of nutrition and binding it to Intrinsic Factor (IF) are processes that take place in the stomach. Furthermore, IF is produced by cells in the stomach wall. In patients who undergo an esophagectomy with gastric tube reconstruction (GTR) for esophageal carcinoma, part of the stomach is removed. Also, a vagotomy is performed, which reduces the production of gastric acid by the stomach endothelium.

One of the possible adverse effects of the operation is that, in the long term, patients can develop a vitamin B12 deficiency. Possible contributing factors for this are an absolute shortage of IF or perhaps a shortage of gastric acid, which will lead to a reduced extraction of vitamin B12 out of nutrition.

Earlier studies already showed an increased prevalence of vitamin B12 deficiency in patients who underwent gastric reduction surgery because of morbid obesity.

Vitamin B12 deficiencies can be symptomatic, in most cases resulting in a reversible macrocytic anemia, but can also result in irreversible neurological damage. Nowadays, screening for vitamin B12 deficiency in patients after esophagectomy with GTR is not common practice.

For this study, we hypothesized that there is a higher prevalence of vitamin B12 deficiency in patients who underwent esophagectomy with GTR.

Study objective

Objective of this study is to determine the prevalence of vitamin B12 deficiency among patients who underwent esophagectomy with GTR. The following specific research questions have been defined:

- What is the prevalence of vitamin B12 deficiency in patients with esophageal carcinoma prior to esophagectomy?
- What is the prevalence of vitamin B12 deficiency in patients after esophagectomy with GTR?
- In what period after esophagectomy do patients develop a vitamin B12 deficiency?
- How many of the found deficiencies are symptomatic and thus need immediate vitamin B12 supplementation?

Study design

Prospective, multi center study.

Patients who are visiting the outpatient clinic in follow-up after undergoing esophagectomy with GTR or patients placed on the waiting list for this procedure will be asked to participate in the study. If patients decide to participate, a blood sample will be taken during follow-up in the out-patient clinic. These samples will be investigated for vitamin B12 deficiency. Patients who are included in the study before their operation will also donate three blood samples on the day of admission before operation. Furthermore, patients will be required to fill in a questionnaire to provide insight in their dietary intake of vitamin B12.

Patient's participation will stop in case of:

1. A vitamin B12 deficiency is found in the patient.
2. A patient has completed the 5 year follow up after his/her esophagectomy.

In case a vitamin B12 deficiency is found in a patient, he/she will be referred back to his/her General Practitioner for further treatment.

Study burden and risks

The burden on patients who participate in the study will be limited to the out-patient clinic visits that will be prolonged by 5 minutes per visit, the time that is needed to take the extra blood samples.

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

- Esophageal carcinoma for which esophagectomy with gastric tube reconstruction has been performed or will be performed in the near future.
- Signed Informed Consent.
- Available for follow-up
- Age > 18 years.

Exclusion criteria

- Treatment with any kind of vitamin B12 within the last two months.
- Not able to fill out a questionnaire in Dutch.

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Prevention

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 10-07-2010

Enrollment: 190

Type: Actual

Ethics review

Approved WMO

Date: 23-06-2010

Application type: First submission

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date: 27-01-2011

Application type: Amendment

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date: 21-07-2011

Application type: Amendment

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date: 06-12-2011

Application type: Amendment

Review commission:

METC Erasmus MC, Universitair Medisch Centrum Rotterdam
(Rotterdam)

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
CCMO	NL31089.078.10