Pilot feasibility study of Ferinject® in patients with esophageal cancer

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The objective of this pilot study is to investigate wether:- Increased Hb levels prior to the operation can prevent blood transfusions preoperative, blood transfusions have a negative effect on the survival of cancer patients- Treatment with...

Ethical review	Not approved
Status	Will not start
Health condition type	Anaemias nonhaemolytic and marrow depression
Study type	Observational invasive

Summary

ID

NL-OMON37387

Source
ToetsingOnline

Brief title
ARCHIE-1

Condition

- Anaemias nonhaemolytic and marrow depression
- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal therapeutic procedures

Synonym
anemia

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Academisch Medisch Centrum,Vifor Pharma

Intervention

Keyword: Esophageal cancer, Iron deficiency anemia, Iron therapy

Outcome measures

Primary outcome

Primary Endpoint:

Number of Hb responders

- Hb responder: increase in Hb * 1.2 mmol/L or reaching normal value normal

value Hb (Hb = 7.5 mmol/L in women and Hb = 8.1 mmol/L in men within 3 weeks

after start of treatment

- SAE's van Ferinject®

Secondary outcome

Secondary Endpoints

- The number of blood transfusions peri-operative

- (S)AE*s (using Vifor Pharma forms)

- Shorter hospital stay due to participation in fast track recovery during

admission

- Quality of life (using the SF-36 questionnaire) during every timepoint

starting from treatment

- Increased Hb levels during every timepoint starting from treatment

Study description

Background summary

Esophageal cancer has an incidence of around 2000 times per year in the Netherlands. The life time prevalence is around 1.5% in men and 0.5% in women.

The patients are often diagnosed in a late stadium of the disease and at higher age (women older then men). The treatment of esophageal cancer consists of radio-chemotherapy (RCT) followed by a transhiatal / transthoracic esophagus cardia resection, which is performed about 500 times a year in the Netherlands. The overall physical condition of these patients decreases due to a decreased food intake and weight loss. They also often suffer from an iron deficiency anemia (IDA) due to a combination of factors. The average hemoglobin (Hb) level when these patients first visit a MDL physician is about 5.5-7.5 mmol/L.

This pilot study will investigate the effect of intravenous iron suppletion (Ferinject®) in patients with an IDA due to esophageal cancer. The standard treatment for IDA is oral iron suppletion, which is slow or (peri-operative) blood transfusion, which should be avoided according to current insights.

Currently these patients are not treated for their IDA in the pre-(R)CT and pre-operative stage. The focus of this pilot study is the actual increase in the absolute Hb level relative to the baseline and the possible side effects of Ferinject®. In addition, the quality of life peri-operative, the time in the hospital, the post-operative complications (like anastomotic leakage and pneumonia) and the number of blood transfusions will be monitored.

Study objective

The objective of this pilot study is to investigate wether:
- Increased Hb levels prior to the operation can prevent blood transfusions preoperative, blood transfusions have a negative effect on the survival of cancer patients
- Treatment with Ferinject increases Hb levels at the start of (R)CT and during the preoperative period
- Increased Hb levels at the start of (R)CT can cause the patient to become fitter and better be able in doing her/his exercises
- Treatment with Ferinject prior to the operation can be linked to less postoperative complications lik anastomotic leakage and pneumonia
Secondary objectives
- Better performance in the fast track recovery system because of the increased Hb level, which implies a decrease in hospital stay (mean hospital stay = 8-13 days)

Study design

A pilot study in 20 patients with esophageal cancer to assess the feasibility of intravenous iron therapy, therefore this pilot does not use a control group.

Ferinject® will be administered in case of:
- Hb < 7.5 mmol/L in women
- Hb < 8.1 mmol/L in men

In a dose depending on the Hb level and body weight during the first intake pre (R)CT and pre-surgery. . The purpose is 1 point Hb increase per occasion * dose determination 1000 mg Fe depending on Hb level and body weight. A strong deviation in MCV, ferritine and transferrin saturation (TSAT) can be a criteria for exclusion.

Inclusion criteria:
- Potentially operable and resectable patients with esophageal cancer
- Age 18 year and older
- Hb < 7.5 mmol/L in women and Hb < 8.1 mmol/L in men
- TSAT < 20%, Ferritine < 100 µg/L * absolute iron deficiency
- TSAT < 20%, Ferritine > 100 µg/L * functional iron deficiency

Exclusion criteria:
- T4 carcinomas
- Inoperable due to comorbidity or ASA IV
- Irresectability
- Metastasis
- Erythropoiesis stimulating agents within 3 months before screening
- Ferritine > 500 µg/L

Study burden and risks

nvt

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

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Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Will not start
Start date (anticipated):	01-09-2012
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Ferinject®
Generic name:	Ferric Carboxymaltose
Registration:	Yes - NL intended use

Ethics review

Not approved

Date:	15-07-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
EudraCT	EUCTR2012-002885-11-NL
CCMO	NL39897.018.12