A randomised, open-label clinical trial assessing the efficacy of octreotide to decrease iron infusion and blood transfusion requirements in patients with refractory anaemia due to gastrointestinal bleeding from angiodysplasias.

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To assess the efficacy of octreotide in decreasing the need for iron infusions or blood transfusions in patients with refractory gastrointestinal bleedings due to small bowel angiodysplasias despite endoscopic intervention.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal haemorrhages NEC
Study type	Interventional

Summary

ID

NL-OMON44271

Source
ToetsingOnline

Brief title
OCEAN-study

Condition

- Gastrointestinal haemorrhages NEC

Synonym
angiodysplasia, vascular malformation

Research involving
Human

Sponsors and support

Primary sponsor: Maag-, darm- en leverziekten
Source(s) of monetary or material Support: Ministerie van OC&W,Novartis Pharma B.V.

Intervention

Keyword: angiodysplasias, bloodtransfusions, gastrointestinal bleedings, octreotide

Outcome measures

Primary outcome

The percentual decrease in blood and iron requirements between the year prior

to inclusion and the treatment period of one year.

Percentual decrease = (number of blood transfusions and iron infusions in the

year prior to inclusion -

number of blood transfusions and iron infusions during the study period) /

number of blood and iron infusions in the year prior to inclusion.

The percentual decrease will be compared between the intervention and control

arm.

All blood transfusions that are given with another indication than

gastrointestinal blood loss are registered, but excluded for analysis for the

primary outcome.

Secondary outcome

* Percentage of hemoglobin increase from baseline until end of treatment for

patients treated with octreotide compared to the control group

* The mean difference in hemoglobin level from baseline until end of treatment

for patients treated with octreotide compared to the control group

* Number of patients requiring red blood cell transfusions from baseline until end of treatment for patients treated with octreotide compared to the control group

* Number of patients requiring other transfusions or medication to correct coagulation between baseline until end of treatment for patients treated with octreotide compared to the control group (see *standard of care*)

* The change in number and severity of bleeding episodes (see for definition section 4.3.2) between start and end of treatment for patients treated with octreotide compared to the control group

* The change in number of patients free of rebleeding between start and end of treatment for patients treated with octreotide compared to the control group

* Reduction in oral iron requirement between start and end of treatment for patients treated with octreotide compared to the control group (see for definition section 4.3.3 *standard of care*)

* The change in level of serum ferritin between baseline until end of treatment for patients treated with octreotide compared to the control group

* The number and type of adverse events (cardiac, pulmonary, neurological, other) between the control and treatment arm during the treatment period F(1)

* Difference in number of hospitalizations, ICU admissions and duration of hospitalization between the control and treatment arm during the treatment period F(1)

* The need for rescue therapy using argon plasma coagulation, coiling or surgery compared between the control and treatment arm during the treatment

period F(1)

* Change in Quality of Life as measured by SF36 and PSQ-An questionnaire

between baseline and end of treatment for patients treated with octreotide

compared to the control group

* Mortality and cause of death compared between the control and treatment arm

during the treatment period

Study description

Background summary

Gastrointestinal angiodysplasias are an important cause of difficult to manage bleeding, especially in older patients. Some patients are transfusion dependent due to rebleedings despite endoscopic intervention. In small cohort studies octreotide appears to decrease the bleeding episodes in those patients.

Study objective

To assess the efficacy of octreotide in decreasing the need for iron infusions or blood transfusions in patients with refractory gastrointestinal bleedings due to small bowel angiodysplasias despite endoscopic intervention.

Study design

Multicenter, randomised, open-label intervention study.

Intervention

The intervention group receives 40 mg Sandostatin LAR once every four weeks for 52 weeks. The control group receives standard of care for 52 weeks.

Study burden and risks

The burden consist of extra vistis, 3x physical examination and 6x blood samples, and fill in two questionnaires 3 times. Half of the patients will be exposed to the somatostatin analogue Sandostatin LAR and thereby are at risk for the known side-effects. The potential benefit for participating patients is that Sandostatin may reduce the need for blood transfusions by decreasing the

number of rebleeds in these patients.

Contacts

Public
Selecteer

Geert Grooteplein-Zuid 10
Nijmegen 6525 GA
NL
Scientific
Selecteer

Geert Grooteplein-Zuid 10
Nijmegen 6525 GA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients with refractory anaemia due to gastrointestinal bleeding from angiodysplasias without any other possible source of bleeding, who are blood transfusion or iron infusion dependent despite endoscopic intervention and oral iron supplementation.
1. Diagnosis of angiodysplasia is made by upper, lower gastrointestinal endoscopy, video capsule or enteroscopy. Single or multiple 2-5 mm flat bright red spots with round uniform or slightly irregular margins, or lesions appearing as raised and reddened areas with a distinctly irregular margin, when larger than 5 mm are seen.
2. Transfusion dependent: at least 4 blood transfusions or iron infusions in the year before inclusion, despite an attempt to supplement iron orally.

3. Failure of endoscopic therapy: at least one attempt with single balloon enteroscopy or dubbel balloon enteroscopy to coagulate the angiodysplasias with APC within the year of diagnosis of symptomatic AD.

Exclusion criteria

-age < 45 years
-liver cirrhosis Child-Pugh C, liver failure or diagnosed portal hypertension
-previous unsuccessful treatment with octreotide for the same indication (refractory anaemia due to angiodysplasias)
-current thalidomide treatment which is effective (no blood transfusion dependency)
-severe diseases with life expectancy < 1 year
-patients with left ventricular assist devices (LVAD*s)
-Rendu-Osler-Weber
-pregnancy or nursing women
-uncontrolled diabetes as defined by HbA1C >64 mmol/ml, despite adequate therapy
-hereditary hemorrhagic diseases or haematological disorders with active treatment
-patients with a known hypersensitivity to SST analogues or any component of the sandostatin LAR formulations
-symptomatic cholecystolithiasis
-non-malignant medical illnesses that are uncontrolled or whose control may be jeopardized by the treatment with this study treatment
-systemic cancer currently undergoing chemotherapy or radiation therapy
-refusal to enter the study
-no understanding of Dutch or English

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-09-2015
Enrollment:	62
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Sandostatin LAR
Generic name:	Octreotide
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	27-08-2015
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	09-09-2015
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	29-02-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	28-10-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	29-07-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	17-02-2021

Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	EUCTR2014-004032-19-NL
ClinicalTrials.gov	NCT02384122
CCMO	NL50514.091.14

Study results

Date completed:	22-04-2022
Actual enrolment:	62

Summary results
Trial is onging in other countries