The effect of chemotherapy on coagulation in patients with locally advanced or metastasized pancreatic cancer

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To determine whether FOLFIRINOX (5-fluorouracil, irinotecan and oxaliplatin) chemotherapy results in an increase of inflammation-mediated procoagulant blood factors; to determine whether CCX872-B, a CCR2-inhibitor, is able to inhibit this increase...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Observational invasive

Summary

ID

NL-OMON41433

Source
ToetsingOnline

Brief title
Effect of chemotherapy on coagulation

Condition

- Miscellaneous and site unspecified neoplasms benign
- Embolism and thrombosis

Synonym
"blood clotting", "coagulation"

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: chemotherapy, coagulation, pancreatic cancer, venous thrombosis

Outcome measures

Primary outcome

- Increase of procoagulant microparticles during chemotherapy

- Source of procoagulant microparticles

Secondary outcome

- Levels of coagulation markers during chemotherapy

- Levels of inflammation markers during chemotherapy

- Association between inflammation and coagulation

Study description

Background summary

Cancer is associated with an increased risk of venous thromboembolism. Especially in patients with locally advaned or metastatic pancreatic cancer the risk is high. This risk is further increased by chemotherapeutic treatment. It is unclear in what way chemotherapy contributes to hypercoagulability. We hypothesize that chemotherapy-induced hypercoagulability is caused by systemic inflammation with leukocyte activation, release of procoagulant microparticles and subsequent acivation of the coagulation cascade.

Study objective

To determine whether FOLFIRINOX (5-fluorouracil, irinotecan and oxaliplatin) chemotherapy results in an increase of inflammation-mediated procoagulant blood factors; to determine whether CCX872-B, a CCR2-inhibitor, is able to inhibit this increase of inflammation-mediated procoagulant blood factors

Study design

Exploratory observational study

Study burden and risks

Burden:
Patients receiving FOLFIRINOX only are asked to donate extra blood (22.4-25.1 mL) 8 times during chemotherapeutic treatment (total duration: 12 weeks). Patients receiving FOLFIRINOX and CCX872-B are asked to donate blood (5.4 mL) at 3 time points during 1 month of chemotherapeutic treatment. Blood is collected from the port-a-cath system which is already punctured at those times as part of regular patient care. Patients do not need to be punctured additionally. Furthermore, non-invasive ultrasound imaging of both legs will be performed in patients receiving FOLFIRINOX only two times during the study in order to screen for asymptomatic venous thrombosis. These investigations are painless and take about 20-30 minutes. Ultrasound imaging will be performed at times when the patient is already visiting the hospital as part of regular patient care. Patients do not need to visit the hospital more often.
Diseased and healthy control patients are asked to donate blood (25.1 mL by vein puncture) only once.

Risks:
There's a chance of diagnosing an asymptomatic deep or superficial venous thrombosis on routine ultrasound imaging of the legs. Treatment with low-molecular-weight heparin and stockings may be started to prevent extension of the thrombus, physical complaints and a pulmonary embolism. The anticoagulant treatment increases the risk of bleeding. The decision whether to treat is dependent on the site and extension of the thrombus and the estimated risk of bleeding.

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

• Ductal adenocarcinoma of the pancreas confirmed by histology or cytology
• Locally advanced or metastasized disease
• Planned for first line FOLFIRINOX chemotherapy with or without CCX872-B
• Chemotherapy naïve
• Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
• 18 years of age or older
• Fully capable of making health related decisions
• Written informed consent

Exclusion criteria

• Current prophylactic or therapeutic anticoagulant therapy
• Current use of anti-inflammatory drugs
• Renal insufficiency with estimated glomerular filtration rate < 30 mL/min before start of chemotherapy
• Venous thromboembolism < 3 months prior to chemotherapy

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-01-2014
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	07-01-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-08-2015
Application type:	Amendment
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
CCMO	NL46437.018.13