Discovery of tumor markers through platelet proteomics

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

Summary

ID

NL-OMON40446

Source
ToetsingOnline

Brief title
Platelet tumor markers

Condition

- Miscellaneous and site unspecified neoplasms benign

Synonym
Cancer, malignancy

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W,NWO Mozaiek

Intervention

Keyword: Angiogenesis, Cancer, Platelets, Proteomics

Outcome measures

Primary outcome

Net change in platelet angiogenic proteome after surgery.

Secondary outcome

None

Study description

Background summary

A crucial element in the process of tumor growth and progression is angiogenesis, the formation of new blood vessels. Although far from fully understood, there is currently a large body of documentation on plasma and serum levels of various angiogenesis regulatory proteins and their predictive and prognostic values. However, the measurement of growth factors and their use as a diagnostic have proved to be difficult, as plasma levels of these agents are only elevated when there is a very high tumor burden. While clearly associated to parameters of cancer growth and progression, the value of these angiogenesis factors and their use as biomarkers for prognosis, has thus far been limited.

Over the last decade it has become clear that platelets may also play an important role in (tumor) angiogenesis and malignancies. Platelets contain a broad spectrum of angiogenesis regulating proteins, both pro- and anti-angiogenic, which they actively take up from plasma and sequester in platelet granules. In addition, various mouse models have shown that concentrations of angiogenesis regulatory factors in platelets are modified by the presence of malignant tumor growth. Even microscopic (<1.0mm) non-angiogenic tumors have been shown to have a significant effect on the angiogenic and angiostatic content of platelets.

Study objective

The objective of the study is to identify potential platelet-derived angiogenic and angiostatic tumorbiomarkers.
Initially platelet proteomics will be used to detect potential tumormarkers.

Subsequently, these potential tumorbiomarkers will be confirmed with an ELISA (Enzyme-linked Immunosorbent Assay) in platelets and platelet free plasma of 150 patients who are already being included in a different studie (the *eTA-study onderzoeksproject nr. 114117).

Study design

In this observational study a total of 20 healthy individuals and 20 patients with stage I&II lung and pancreatic cancer will be included. From the patients 20ml of blood is collected before and after surgery. 10 ml is separated in platelet pellet and platelet free plasma and stored at -80°C until ELISA. The remaining 10ml of blood will be used for proteomics to find potential platelet-derived tumor biomarkers. The potential tumor biomarkers found will be confirmed with an ELISA (Enzyme-linked Immunosorbent Assay) in platelets and platelet free plasma of 150 patients who are already included in a different studie (the *eTA-study onderzoeksproject nr. 114117).

Study burden and risks

The aim is to keep the extent of the burden and risks to a minimum. Therefore, the first blood collection is performed during regular blood collection. This prevents extra vena puncture. The second blood collection occurs two months after the operation. To minimize the burden, patients are offered to give blood at home. In this case the researcher will visit them at home to collect blood. Patients can also choose to come to the hospital to given blood.

The risks are the same as during regular blood drawing using vena puncture. There is a slight chance of hematoma development. No other risks of disadvantages are known for this research.

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

-Patients with stage I&II lung and pancreatic malignancies who are eligible for surgical resection.
-Age >18 years
-Histologically confirmed adenocarcinoma
-Hb >5.6 mmol/L

Exclusion criteria

-Use of any platelet-influencing drug during two weeks prior to blood collection
-Patients with congenital platelet disorder
-Blood or platelet transfusion during two weeks prior to blood collection
-Inflammatory diseases or diabetes
-Serious non-healing wound, ulcer, or bone fracture
-Pregnancy or breast-feeding
-Interference with other research projects

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial

Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-09-2014
Enrollment:	44
Type:	Actual

Ethics review

Approved WMO

Date:	18-06-2014
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL46605.068.13