

Influence of anticoagulant therapy on platelet mRNA profiling

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To evaluate the influence of anticoagulant treatment on the platelet mRNA profile in patients in whom anticoagulation is initiated.

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

Summary

ID

NL-OMON50253

Source

ToetsingOnline

Brief title

Influence of anticoagulation on platelet mRNA profiling

Condition

- Miscellaneous and site unspecified neoplasms benign
- Embolism and thrombosis

Synonym

atrial fibrillation, venous thromboembolism

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

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

Intervention

Keyword: anticoagulant therapy, platelet mRNA profiling

Outcome measures

Primary outcome

Correlation between the platelet mRNA profile, expressed as mean log2-transformed counts per million, before anticoagulation and during anticoagulation.

Secondary outcome

Differences in plasma levels of coagulation markers before and during anticoagulation, including D-dimer and endogenous thrombin potential.

Study description

Background summary

Platelet mRNA sequencing has recently been introduced as a promising biomarker for cancer.¹ The concept revolves around the alteration of the platelet mRNA profile in the presence of cancer through several mechanisms: (1) transfer of oncogenic mRNA to platelets mediated by extracellular vesicles; (2) specific splicing of precursor mRNA in platelets induced by platelet activation; (3) splice events in response to signals released by cancer cells, and (4) direct mRNA ingestion by platelets. Following these events, the platelets are then referred to as *tumour-educated platelets*.

The mRNA profile of tumour-educated platelets appears to be significantly different from the profile of healthy donors, which potentially allows for its use as a pan-cancer diagnostic tool. In a first study of 228 patients with various cancer types and 55 healthy donors, platelet mRNA sequencing was associated with a sensitivity of 97% and a specificity of 94% for detecting cancer (Best et al, Cancer Cell 2015).

Recently, the PLATO-VTE study was initiated to evaluate the diagnostic accuracy of platelet mRNA sequencing to detect occult cancer in patients with unprovoked venous thromboembolism (VTE) (NL57256.018.16; AMC METC 2016_110). For the interpretation of the test results, it is crucial that we know the potential influence of anticoagulant therapy on the test.

Study objective

To evaluate the influence of anticoagulant treatment on the platelet mRNA profile in patients in whom anticoagulation is initiated.

Study design

This is an observational, prospective cohort study that will enroll patients in whom anticoagulation is initiated, including those with new onset atrial fibrillation and venous thromboembolism. A total of 12.7 cc blood will be drawn in three tubes before initiation of anticoagulation and at 10 ± 3 days (see Appendix 1 for details). Blood will be used for testing of coagulation markers and platelet mRNA profiling.

Study burden and risks

The burden for patients consists of two blood withdrawals of 12.7cc; one at baseline and one after a minimum of 10 days.

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

- Age 18 years or older
- Objectively confirmed, new onset atrial fibrillation or acute VTE (deep vein thrombosis or pulmonary embolism)

Exclusion criteria

- Anticoagulant therapy at the time of the first blood withdrawal
- Inability for blood withdrawal;
- Inability or refusal to provide written informed consent

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 12-09-2017

Enrollment: 38

Type: Actual

Ethics review

Approved WMO

Date: 06-07-2017

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
CCMO	NL60989.018.17