Whole blood thrombin generation, platelet activation test and platelet-monocyte complex formation to predict hypercoagulability in patients with multiple myeloma

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To estimate the prothrombotic phenotype of patients with MM, on treatment with IMiD, using whole blood thrombin generation (WB-TG), platelet activation assays and PMC formation.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Haematopoietic neoplasms (excl leukaemias and lymphomas)
Study type	Observational invasive

Summary

ID

NL-OMON48375

Source
ToetsingOnline

Brief title
Whole blood thrombin generation in patients with multiple myeloma

Condition

- Haematopoietic neoplasms (excl leukaemias and lymphomas)
- Haematopoietic neoplasms (excl leukaemias and lymphomas)

Synonym
cancer of plasma cells, Plasma cell myeloma

Research involving
Human

Sponsors and support

Primary sponsor: Synapse Research Institute
Source(s) of monetary or material Support: Synapse Research Institute betaalt het onderzoek

Intervention

Keyword: Hypercoagulability, Multiple myeloma, Platelets, Whole blood thrombin generation

Outcome measures

Primary outcome

Thrombin generation in whole blood, platelet activation and platelet-monocyte

complex formation in patients with MM and in controls.

Secondary outcome

Not apllicable

Study description

Background summary

Patients with multiple myeloma (MM) have an increased risk of venous thromboembolism (VTE). During the past decade, the introduction of oral immunomodulatory drugs (IMiDs), like thalidomide and lenalidomide, has improved the clinical outcome of patients diagnosed with MM. However, a high rate of thromboembolic complications has been observed when using these agents, especially in combination with chemotherapy and high-dose corticosteroids, which has led to increased clinical awareness of VTE and research focus on the topic.
Thrombin generation (TG) in platelet poor plasma (PPP) is a research tool in the field of thrombosis and hemostasis. TG is currently the best, in vitro, test to predict the risk of (recurrent) thrombosis. Recently, we developed an assay to measure TG in whole blood which gives global insight in the blood cells mediated coagulation potential. Furthermore, in patients with MM platelets are more activated. When platelets are activated, they form complexes with monocytes. These platelet-monocyte complexes (PMCs) represent an early process in atherothrombosis and inflammation. Inflammation also occurs at the endothelial level, contributing to atherosclerotic plaque formation.

Study objective

To estimate the prothrombotic phenotype of patients with MM, on treatment with IMiD, using whole blood thrombin generation (WB-TG), platelet activation assays and PMC formation.

Study design

A case-control study

Study burden and risks

The burden associated with the participation in this study is a venapuncture in the arm and the subsequent collection of 21 ml of blood. The risks associated with a venapuncture are minimal, bruising at the puncture site may occur.

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

For all participants (patients and controls):
- Subjects of both gender
- Age *18
- Written informed consent from the subject

Patients with Multiple Myeloma:
- Stable condition
- Diagnosis of Multiple Myeloma
- On active treatment with IMiD
- Patient of the Meander Medical Center

Exclusion criteria

For all participants (patients and controls):
- Age below 18
- Known abnormalities of the coagulation system
- Pregnancy
- The use of anti-coagulant drugs (low molecular weight heparin (LMWH), vitamin K antagonists (VKAs) and direct oral anticoagulants (DOACs))
- Active infection, bleeding or other systemic diseases
For controls (relatives: family or no-family):
- Active malignancy
- Personal history of bleeding or thrombotic events

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):	20-01-2020
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	18-09-2019
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	NL68552.068.19

Study results

Date completed:	11-03-2020
Actual enrolment:	42

Summary results
Trial ended prematurely