Predicting platelet age in an intelligent way

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Primary Objective:Part 1: to characterize platelets of patients with Lowe syndrome using superresolution microscopy.Part 2: to characterize platelet age in patients receiving chemotherapy for AML using artificial intelligence techniques.Secondary…

Ethical review	Approved WMO
Status	Completed
Health condition type	Platelet disorders
Study type	Observational non invasive

Summary

ID

NL-OMON53631

Source
ToetsingOnline

Brief title
Predicting platelet age in an intelligent way

Condition

- Platelet disorders

Synonym
low platelet count, thrombocytopenia

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: ageing, artificial intelligence, platelets

Outcome measures

Primary outcome

For Part 1 as well as Part 2: platelet characteristics using staining of alpha

tubulin and VWF and SPARC.

Secondary outcome

NA

Study description

Background summary

Platelets are small, anucleated cells with their primary physiological role to repair vascular damage (hemostasis) and initiate thrombus formation in response to vascular injury. During ageing platelets lose platelet surface glycoproteins and proteins involving platelet granulation, secretion and regulated exocytosis time as we have previously shown.

Diminished function due to storage, e.g. the platelet storage lesion (PSL), has major impact on transfusion medicine. Also deficiency in platelet function or count will lead to bleeding complications, like in patients with immune thrombocytopenia (ITP). Predicting apparent platelet age will determine whether platelets are relatively young and thus rapidly cleared, or older assuming due to decreased production. Patients with rapid clearance may benefit more from treatment with clearance inhibitors (glucocorticoids and Rituximab), where patients with older platelets may benefit from treatment to enhance production such as TPO-RA. In our preliminary in vitro studies we could separate young and old platelets using novel platelet imaging techniques and artificial intelligence techniques.

In this research proposal we will first characterize platelets in vivo in patients with a platelet disorder (Lowe syndrome). Additionally we will characterize young and old platelets in vivo in patients with acute myeloid leukemia (AML) receiving chemotherapy. Results of this project will lead to better understanding of platelets of patients with a platelet disorder (part 1), and will also generate new insights into treatment options for patients

with thrombocytopenia (part 2).

Study objective

Primary Objective:
Part 1: to characterize platelets of patients with Lowe syndrome using superresolution microscopy.
Part 2: to characterize platelet age in patients receiving chemotherapy for AML using artificial intelligence techniques.

Secondary Objectives:
Part 1: to evaluate platelet function using flowcytometry and aggregometry.
Part 2: Not applicable

Study design

Single center observational study

Study burden and risks

The burden for Lowe patients in Part 1 is one blood draw during routine clinical test. The amount of blood is based on the weight, with a maximum of 16mL. This is lower than the maximum amount of blood recommended (appendix 1). The burden for clinical AML patients in Part 2 is 4,5mL blood draw during routine clinical test at day 0, 3, 5 and 7 after chemotherapy. And also 1 blood draw during repopulation, defined as first timepoint of increase of platelet count and >10 days after platelet transfusion. Finally during steady state one blood draw, defined as the time when platelet count >150x10E9/L.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)

Inclusion criteria

Part 1:
Patients diagnosed with Lowe syndrome
All ages

Part 2:
Patients diagnosed with AML
After first remission induction (RI) cycle
In complete remission after first RI cycle

Exclusion criteria

Part 1:
patients with a known bleeding disorder
Unwilling to give informed consent
Patients using anticoagulants

Part 2:
patients receiving platelet transfusion in the study period
unwilling to give informed consent
Patients using anticoagulants

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	01-05-2023
Enrollment:	8
Type:	Actual

Ethics review

Approved WMO

Date:	01-05-2023
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL82620.078.22