Studying extracellular vesicles in immune thrombocytopenia

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Recent data shows that patients with ITP have increased levels of the so called platelet-extracellular-vesicles (EVs). In this pilotstudy we would like to characterize these EVs and investigate whether they play a pathogenic role in the maintenance...

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

Summary

ID

NL-OMON57039

Source
ToetsingOnline

Brief title
Extracellulair vesicles in ITP

Condition

- Platelet disorders

Synonym
Immune 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: ITP, Vesicles

Outcome measures

Primary outcome

Concentration of EVs in ITP patients; Wilcoxon signed rank tests will be used

to compare EV concentrations between groups. Of interest are EVs derived from

platelets (CD61+), activated platelets (CD62p+) and erytrocytes (CD235a+).

Secondary outcome

Association of (platelet-derived) EVs with age, sex and current/past therapy.

Study description

Background summary

Primary Immune Thrombocytopenia (ITP) is an acquired isolated trombocytopenia (platelet count < 100 x 109/l) without an underlying disease or cause of the thrombocytopenia. ITP can occur due to increased platelet clearance medicated by autoantibodies, decreased platelet production and T-cell mediated processes. The incidence of ITP is approximately 50/1.000.000. The prevalence is equally distributed between male and female, except for the age category 30-60 years where the prevalence of ITP is higher in female. ITP is classified according the duration of the disease: acute ITP, persistent ITP (3-12 months) and chronic ITP (>12 months). Most important symptoms are bleeding and decreased health related quality of life. Clinical symptoms may vary between none to life threatening bleedings. Most bleeding symptoms occur with a platelet count <30x109/L although there is no relationship between platelet count and bleeding severity.

Due to the large heterogeneity between patients it is difficult to predict disease severity and therapy response. A better understanding of the underlying pathology is most important to improve patient care.
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Study objective

Recent data shows that patients with ITP have increased levels of the so called

platelet-extracellular-vesicles (EVs). In this pilotstudy we would like to characterize these EVs and investigate whether they play a pathogenic role in the maintenance of ITP. Also we would like to measure the association with therapy response.

Study design

single center observational pilotstudy. Test will be performed at Sanquin Amsterdam and patients will be recruited at Erasmus MC.

Study burden and risks

The burden for ITP patients is one blood draw during routine clinical test. The amount of blood is 9mL in total (One 3mL EDTA tube and two 3mL citrate tubes).

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

's-Gravendijkwal 230
Rotterdam 3015 CE
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

's-Gravendijkwal 230
Rotterdam 3015 CE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Adult patients with ITP
Informed consent will be obtained

Exclusion criteria

Patients with secondary ITP
Patients with antiplatelet therapy

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):	15-10-2024
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	08-10-2024
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	NL87357.078.24