investigation of the relation between trombo-embolic events and microparticles in essential thrombocythemia and polycythemia vera patients

Published: 23-10-2007
Last updated: 09-05-2024

To determine the levels, cellular origin and procoagulant function of microparticles in ET and PV, and to explore the existence of a correlation with jak2V617F mutation, medication and vascular events.

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

Summary

ID

NL-OMON31395

Source
ToetsingOnline

Brief title
Microparticles in ET&PV patients

Condition

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

Synonym
blood disease, myeloproliferative disorders

Research involving
Human

Sponsors and support

Primary sponsor: Onze Lieve Vrouwe Gasthuis
Source(s) of monetary or material Support: onderzoeksbugdet interne geneeskunde en HKCL

Intervention

Keyword: essential thrombocythemia, microparticles, polycythemia vera, thrombosis

Outcome measures

Primary outcome

Number of Annexin V positive microparticles in patients and controls as well as

the expression of different antibodies in this Annexin V positive.

Endogene trombine potential of patients and controls.

We will describe the relationship of these microparticles with medication,

jak2V17 mutation and history of thrombo-embolic events in patients and controls

Secondary outcome

We will describe the relation between these microparticles and Von Willebrand

factor antigen and propeptide, E-selectin, thrombocytes, age and gender.

Study description

Background summary

Thromboembolic complications are common in patients with Essential Thrombocythaemia (ET) and Polycythemia Vera (PV). Their pathogenesis is not completely explained, neither by platelet count, nor by platelet function although abnormalities have been described. We hypothesize a role for cellular microparticles (MPs), since they are known to be elevated in thromboembolic diseases, like myocardial infarction and venous thromboembolism.

Study objective

To determine the levels, cellular origin and procoagulant function of

microparticles in ET and PV, and to explore the existence of a correlation with jak2V617F mutation, medication and vascular events.

Study design

We will analyse samples of 20 patients meeting the WHO criteria for ET, and 30 patients meeting the WHO criteria for PV, and we will analyse 30 controls. We will use previously described methods for flowcytometry to determine number and origin of cellular microparticles.

Study burden and risks

No extra risk or burden for patients.

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 who meet WHO criteria for PV and ET

Exclusion criteria

we have no exclusion criteria

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2007
Enrollment:	80
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL18428.067.07