Bleeding in patients with hemato-oncological disease in relation to platelet function (BOP study)

Published: 07-04-2016
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To assess the relation between bleeding tendency (patients with WHO grade II or more) and platelet function and platelet /count in patients with hemato-oncological disease

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Anaemias nonhaemolytic and marrow depression
Study type	Observational non invasive

Summary

ID

NL-OMON47418

Source
ToetsingOnline

Brief title
BOP study

Condition

- Anaemias nonhaemolytic and marrow depression

Synonym
patients with hemato-oncological disease

Research involving
Human

Sponsors and support

Primary sponsor: Meander Medisch Centrum Amersfoort
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: bleeding, hemato-oncological disease, platelets, transfusion

Outcome measures

Primary outcome

Primary Objective: To assess the relation between bleeding tendency (patients with WHO grade II or more) and platelet function and platelet /count.

Secondary outcome

1. To assess the relation between bleeding tendency (all grades) and platelet function and platelet count.

2. To assess the percentage of days with WHO grade II or more bleeding and platelet function. 3. To assess the relation between vascular damage (endothelial cell markers in plasma) and bleeding tendency (all grades).

4. To assess the bleeding observation score, vascular damage and platelet function in patients upon remission-induction chemotherapy for acute leukemia/ myelodysplastic syndrome and other diseases.

5. To assess the influence of infection (SIRS criteria) on the bleeding observation score, vascular damage and platelet function.

6. To assess the influence of platelet transfusions on the health related quality of life in thrombocytopenic hemato-oncological patients.

Study description

Background summary

Platelet transfusions are generally accepted to prevent and treat bleeding complications in patients with thrombocytopenia due to myelosuppressive

treatment or malignancy. Bleeding is patients with trombocytopenia depends to some extent on the amount of blood platelets present. The amount of platelets in normal individuals is (too) high. The normal count is between 150-350.000. Nevertheless, signs of bleeding are expected when the count is below 30-50.000. Even in the range of a low platelet count, bleeding is very difficult to predict. The platelet count itself is not a good predictor and platelet function is likely to be much more important. Indeed, in a pilot we observed bleeding in patients with immune mediated destruction of platelets to be depended on function, merely than count. In patients with chemotherapy induced thrombocytopenia, bleeding was also dependent on function and not on count. Platelet transfusions are associated with adverse events and are given at high costs. Mild to moderate reactions to platelet transfusions include rigors, fever, and urticaria. These reactions are not life-threatening but can be extremely distressing for the patient. Rarer, but more serious sequelae include: anaphylaxis; transfusion-transmitted infections; transfusion-related acute lung injury; and immunomodulatory effects. Costs involved are considerable (500 euro per unit, total costs in The Netherlands 70 million euro) To improve future transfusion strategies, we will study the relation between bleeding complications and platelet function in patients with thrombocytopenia due to myelosuppressive treatment. A pilot (feasibility) study is already been performed in Meander MC. Platelet function will be measured by a new flowcytometry based assay. This assay is validated for platelet function testing at low platelet count. A pilot (feasibility) study is already been performed in Meander MC. Any strategy that can safely decrease the need for prophylactic platelet transfusions in haematology patients will have significant logistical and financial implications as well as decreasing patients* exposure to the risks of transfusion. A safe strategy in the future with platelet function as a parameter for transfusion instead of platelet count will improve transfusion strategies, with important economic (less transfusions/costs) and clinical (less donor exposition/side effects of transfusion) consequences. In addittion, there is no literature available which evaluates the effect of platelet transfusions on the health related quality of life in this population. To our opinion, this should also be considered before initiating platelet transfusions.

Study objective

To assess the relation between bleeding tendency (patients with WHO grade II or more) and platelet function and platelet /count in patients with hemato-oncological disease

Study design

The relation between bleeding observation score and platelet function will be studied in a multicentre prospective cohort study in 150 patients with hemato-oncological disease. Patients can be included for a maximum of 6 times

during each treatment cycle. Duration: 4 years

Study burden and risks

Minimal risk on bleeding upon venapunction

Contacts

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Scientific
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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.
Expected platelet transfusion support (platelet count <50x10^9/L)
Signed informed consent.
Having a hemato-oncological disease receiving high dose chemotherapy or a stem cell

transplantation

Exclusion criteria

Micro-angiopathic thrombocytopenia (TTP, HUS) and ITP
The use of anti-coagulant drugs or drugs affecting platelet function

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-06-2016
Enrollment:	160
Type:	Actual

Ethics review

Approved WMO Date:	07-04-2016
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	28-06-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	11-09-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	13-12-2018
Application type:	Amendment
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	NL54842.100.15