The BITE study - Bleeding In Thrombocytopenia Explained: A nationwide epidemiological and laboratory case cohort study investigating risk factors for bleeding in hemato-oncology patients

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- Identify hemato-oncology patients and conditions with a high versus a low bleeding risk, by epidemiological research and a short questionnaire. - Investigate the association of bleeding related biomarkers with bleeding.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Haematological disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON55653

Source
ToetsingOnline

Brief title
The BITE study

Condition

- Haematological disorders NEC

Synonym
Hemato-oncological diseases, malignant diseases of the blood.

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Sanquin Research

Intervention

Keyword: bleeding, hemato-oncology patients, platelet transfusion, risk factors

Outcome measures

Primary outcome

- The presence of clinical factors and results of routinely performed

laboratory tests compared between bleeding versus non-bleeding patients.

- Presence of markers for coagulation-, platelet- and endothelial or vascular

dysfunction compared between bleeding versus non-bleeding patients.

Secondary outcome

NA

Study description

Background summary

Hemato-oncological patients treated with intensive chemotherapy receive prophylactic platelet transfusions to prevent bleeding events as soon as their platelet counts drop below 10 x109/L. This platelet count based prophylactic transfusion strategy, however, is both inefficient and often not needed. This is reflected in the high percentage of patients with bleeding despite this strategy (43%), and the high percentage of patients who do not bleed without this strategy (50%). Solely platelet count therefore is not a good predictor for bleeding. Identification of new risk factors and confirmation of already suspected risk factors is essential, and should lead to better prediction and prevention of bleeding. Patients with a high risk profile could be given more effective haemostatic treatments including more efficient transfusion strategies. On the other hand one could consider omitting prophylactic transfusions to low risk patients and conditions. Furthermore, more knowledge

about the pathophysiology of bleeding in hemato-oncology patients is needed.

Study objective

- Identify hemato-oncology patients and conditions with a high versus a low bleeding risk, by epidemiological research and a short questionnaire.
- Investigate the association of bleeding related biomarkers with bleeding.

Study design

Case cohort study, consisting of two parts: an epidemiologically research including short questionnaire (for all patients that meet the inclusion criteria), part B additional blood and urine sampling (only for patients who are admitted for chemotherapy or stem cell transplantation).

Study burden and risks

The epidemiological part of the study does not have burden or health risks: comparison of standard available data between bleeding and non-bleeding patients makes this a non-WMO part of the study, since there is no invasive intervention. The 10-15 minutes questionnaire in this respect is not considered as a burden.
The laboratory part of the study only applies for a subgroup of the included patients and falls under the scope of the WMO. The intervention is the additional to regularly performed citrate anticoagulated blood sampling (maximum 10 samples of 10-15 cc in 4 weeks), as well as weekly urine sampling. Both are considered a minor burden for participants, and the risk of additional blood sampling at regular sampling moments is negligible. Finally, all BITE-study activities in both study parts will not have any consequences on the treatment or monitoring of 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

- Admission in the hospital
AND
- Age >= 18 years
AND
- Hemato-oncology patient, including MDS and AA, admitted for treatment (chemotherapy, SCT) who is (expected to become) thrombocytopenic with platelet counts of < 50 for expected at least 5 days and who will possibly be treated with one or more prophylactic platelet transfusions. (part A and B)
OR
- Hemato-oncology patient who had previous intensive chemotherapy or stem cell transplantation and who is admitted to the hematology ward for disease or treatment related events or complications. (part A only)

Exclusion criteria

- Myeloproliferative disorders

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-12-2018
Enrollment:	1000
Type:	Actual

Ethics review

Approved WMO

Date:	04-04-2018
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	27-07-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	22-10-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	30-01-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	18-12-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	16-02-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL62499.058.17