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Comparison of in vivo outcome following transfusion of dynamic light scattering-screened versus unscreened platelets

Submission date 07/07/2010	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 16/07/2010	**Overall study status** Completed	
Last Edited 16/07/2010	**Condition category** Haematological Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Comparison of in vivo outcome following transfusion of dynamic light scattering-screened versus unscreened platelets in hematologic malignancy: A randomised controlled trial

Acronym
CoDIVO clinical trial

Study objectives
Feasibility Trial
To test whether at least 80% of platelet (PLT) transfusions are provided in a timely manner when the ThromboLUX™ score measurement is incorporated into the current Transfusion Medicine Laboratory (TML) platelet issuance workflow. The time required to measure the ThromboLUX score of a sample is 20 min. With available group and screen result, a delay in turnaround time of up to 1 hour is considered acceptable for urgent requests, and up to 4 hours for routine requests.
Pivotal Trial
The mean 24 hour corrected count increment (as a measure of transfusion outcome) in the experimental group (those receiving platelets with a ThromboLUX DLS score > 15) will be higher than the mean corrected count increment in the control group (those receiving standard of care or platelets with a DLS score ranging anywhere from 0 to 40).

Ethics approval required
Old ethics approval format

Ethics approval(s)
British Columbia Cancer Agency (BCCA) and University of British Columbia (UBC) research ethics board (REB) (ref: H09-02334) approved pending registration of clinical trial; expected Jul 2010.

Study design
Single centre randomized controlled clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Platelet transfusion; hematological malignancy

Interventions
The treating physician will determine the need for platelet transfusion based on symptoms or threshold morning platelet count in accordance with established guidelines. Each enrolled patient will be randomized to the experimental arm or the control arm.
Experimental: Each platelet transfusion provided will have a ThromboLUX score of greater than or equal to 15.
Control: Platelet transfusions provided will be equivalent to current industry standard of care, which is ThromboLUX untested. This group's platelets will have ThromboLUX scores of any value.

Joint/Secondary Sponsor Details:
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Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. 24 hour corrected count increment (CCI24h); the transfusion outcome of each platelet transfusion will be determined by documenting the platelet survival in patient circulation at 24 hours. This is the primary outcome. The corrected count increment (CCI) is an automated calculation using the established formula which cannot be influenced by the software user. CCI will be calculated by the laboratory research assistant from the pre-and post-transfusion platelet counts, normalized to the body surface area.
Corrected count increments (CCIs) are calculated using the following formula:
CCI = (post count pre count) x BSA / platelet dose x 1011
Where body surface area (BSA) is calculated based on patient height and weight using :
BSA [m²] = 0.007184 x Height [cm]0.725 x Weight [kg]0.425
2. Time to next platelet transfusion (hours), or inter-transfusion interval (ITI). Therapeutic or prophylactic platelet transfusions will be requested by the patients physician in accordance with international guidelines. Prophylactic PLT transfusions will be given to afebrile and clinically stable patients with peripheral blood PLT counts below 10 x 109/L and to febrile patients when PLT counts are below 20 x 109/L. In patients with increased risk of bleeding (e.g., before invasive procedures or recent hemorrhage) or ongoing bleeding, PLT transfusions will be administered when peripheral blood PLT counts are below 20 - 50 x 109/L and at physician discretion.
3. World Health Organization (WHO) bleeding score; administered by blinded research nurse daily and at 24 hours post platelet transfusion. The bleeding score will be assigned daily based on the severity of bleeding criteria. The following categories are evaluated:
3.1. No bleeding
3.2. Grade I - very mild bleeding
3.3. Grade II - mild, epistaxis, mucocutaneous, conjunctival bleeding
3.4. Grade III - moderate, greater than II, but not requiring RBC support
3.5. Grade IV - severe bleeding

The ThromboLUX score, produced by the instrument without user intervention, will be correlated to the three outcome measures: 24h CCI, ITI and WHO bleeding score.

Key secondary outcome(s))
1. Additional clinical information, known to impact platelet recovery and survival will be collected for each enrolled patient, including:
1.1. General Clinical Information:
1.1.1. Baseline Data for Enrolled Patients
1.1.2. Diagnosis
1.1.3. Planned Treatment (current admission)
1.1.4. Weight (calculated BSA)
1.1.5. Splenomegaly (Y/N)
1.1.6. HLA antibody screen status (if repeat admission)
1.2. Daily Clinical Data Collection during period of hypoproliferative thrombocytopenia (from

first platelet count <50 x giga/L, or 1st platelet transfusion order, to Bone Marrow recovery (spontaneous platelet count >75 x giga/L)
1.2.1. Bleeding Score by WHO (Administered by blinded study RN)
1.2.2. Temperature (route)
1.2.3. Infection (Y/N) / culture results
1.2.4. Antibiotic therapy
1.2.5. Antifungal treatment
1.2.6. Granulocyte Cell Stimulating Factor (GCSF)
1.2.7. Platelet count
1.2.8. Hemoglobin
1.2.9. Known Graft versus Host (organ(s) and grade)
1.2.10. Coagulopathy (International Normalized Ratio [INR], Partial Thromboplastin Time [PTT], Thrombin Time [TT], Fibrinogen, D dimer if available)
1.2.11. Positive anti-HLA antibody screen or CBS antibody testing (detail/date of sample)
1.2.12. Red Blood Cell (RBC) Transfusion (# units, and indication)
1.2.13. Platelet Transfusion (indication)
1.2.14. Procedure planned/ special notes
1.3. With Each Platelet Transfusion
1.3.1. Time initiated
1.3.2. ABO compatibility
1.3.3. Matched
1.3.4. Major Incompatible
1.3.5. Minor Incompatible
1.3.6. Bidirectional incompatibility
1.3.7. Transfusion Reaction (Type)
1.3.8. 1 hour post platelet count (45-120 min)
1.3.9. 24 hour post platelet count (18-24h)
2. Data Collected for each Platelet concentrate transfused to a study patient (screened or control arm) includes:
2.1. Data provided on product label
2.1.1. Platelet count of product
2.1.2. Type of platelet product (Apheresis or buffy coat pool)
2.2. Data obtained from analysis of sterile sample from platelet bag
2.2.1. Thrombolux score
2.2.2. pH
2.2.3. Morphology
All platelet concentrates will be gamma irradiated prior to issue with VGH Cesium source blood product irradiator. (Canadian Nuclear Safety Commission License No: 03323-2-12-0)
3. Additional testing on existing Patient blood sample post transfusion (for selected transfusion events):
For platelet transfusions where one hour post transfusion platelet count exceeds the sum of pre-transfusion count plus the transfused platelet dose plus two standard deviations, the post transfusion patient EDTA sample will be procured from the hematology laboratory and transferred to the centre for blood research laboratory for further testing. Testing will include CD41 and CD61 by flow cytometry.

Completion date
31/08/2012

Eligibility

Key inclusion criteria
We propose to enrol 200 leukemia and bone marrow transplant inpatients, as frequent recipients of prophylactic and therapeutic platelet transfusions.
All patients >18 years of age with hematologic malignancies on the leukemia and bone marrow transplant ward VGH (T15), undergoing stem cell transplantation or chemotherapy, and expected to require at least one platelet transfusion will be considered for enrolment.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Patients who have received platelet transfusion (outside the CoDIVO study) within the past two weeks
2. Patients known to require Human Leukocyte Antigen (HLA) matched platelet support will be ineligible, due to TML's inability to guarantee availability of HLA matched platelets with TL score >15 in experimental arm
3. Patients with documented splenomegaly will be excluded, because an enlarged spleen causes enhanced platelet removal
4. Unable to provide informed consent
5. Unreliable availability of appropriate English translator (Daily bleeding scores required)
6. Pregnancy
7. Major surgery within the previous two weeks
8. Acute promyelocytic leukemia
9. Idiopathic or Thrombotic thrombocytopenic purpura or Hemolytic Uremic Syndrome

Date of first enrolment
07/09/2010

Date of final enrolment
31/08/2012

Locations

Countries of recruitment
Canada

Study participating centre

Dept of Pathology and Laboratory Medicine
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Sponsor information

Organisation
Vancouver Coastal Health (Canada)

ROR
https://ror.org/04htzww22

Funder(s)

Funder type
Charity

Funder Name
Canadian Blood Services (Canada)

Alternative Name(s)
Société canadienne du sang, Canadian Blood Services - Ontario, lifelineontario, CBS

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Canada

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes