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ABMT-COLL-014 HEPARIN PROTOCOL

1 PURPOSE

1.1 To describe the procedure for using heparin, in addition to Anticoagulant Citrate Dextrose (ACD) Solution A, as an anticoagulant during an apheresis procedure using the Spectra Optia blood cell separator.

2 INTRODUCTION

- 2.1 ACD prevents platelet activation and coagulation as blood moves throughout the extracorporeal unit (tubing set) in an apheresis procedure.
- 2.2 Rapid infusion of ACD during leukapheresis can cause symptoms of citrate toxicity (hypocalcemia), such as mild anxiety, numbness and tingling of the lips and fingers, cramping of the extremity muscles, and could progress to muscle tetany, confusion, and/or disorientation. The addition of heparin to the ACD will significantly decrease the ACD flow rate, decrease the total volume of ACD used during the apheresis procedure, and allow inlet flow to be maximized. The decreased flow of ACD may relieve symptoms of citrate toxicity.
- 2.3 The Heparin Protocol can be initiated for patients or donors whose symptoms are not adequately relieved by intravenous (IV) or oral calcium, at risk for developing citrate toxicity, or who cannot tolerate inlet flow rates in the range of 50-70 milliliters a minutes (mL/min) without symptom relief.
- 2.4 The Heparin Protocol should also be considered for patients who are at high risk of developing problems due to fluid overload, such as cardiac and/or renal patients. The Heparin Protocol will decrease the total volume of ACD used during apheresis, thus decreasing the fluid volume given to the patient during the procedure.
- 2.5 The Heparin Protocol can be initiated following the collection of target plasma volume, if required.
- 2.6 Approximately 10% of the final cellular collection product should contain anticoagulant.
- 2.7 Heparin protocol cannot be used when the patient/donor platelet count is 50,000/microliter or lower.
- 2.8 All procedures are performed using aseptic technique which includes scrubbing the injection sites 15 seconds with alcohol pad.

3 SCOPE AND RESPONSIBILITES

3.1 The apheresis staff are responsible for assessing the patient and donor for signs and symptoms of citrate toxicity during the collection.

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4 DEFINITIONS/ACRONYMS

4.1 ABMT: Adult Blood and Marrow Transplant

4.2 ACD: Anticoagulant Citrate Dextrose

4.3 IV: Intravenous

4.4 HCT: Hematocrit

4.5 mL: Milliliter

4.6 mL/min: Milliliters a Minute

4.7 NMDP: National Marrow Donor Program

4.8 PPE: Personal Protective Equipment

4.9 WBC: White Blood Cell

5 MATERIALS

- 5.1 Heparin vial 10,000 units/10 mL
- 5.2 10ml syringe (Okay to Use)
- 5.3 3ml syringe (Okay to Use)
- 5.4 20-gauge needle (Okay to Use)
- 5.5 Medication Added Label
- 5.6 Alcohol Wipe(s)

6 EQUIPMENT

6.1 NA

7 SAFETY

7.1 Follow all safety related Standard Operating Procedures and wear all necessary Personal Protective Equipment (PPE) when handling potentially hazardous blood and body fluids. PPE includes but is not limited to gloves, surgical mask, gown, face shield or goggles. Hand hygiene will be performed before and after patient contact.

8 PROCEDURE:

- 8.1 Optia Heparin Protocol
 - 8.1.1 If patient has an increased risk of fluid overload or citrate toxicity, check platelet count. Remember the Heparin Protocol cannot be used if the patient/donor's platelet count is 50,000 or lower.

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- 8.1.2 Prime Optia with ACD, and initiate apheresis. Refer to ABMT-COLL-019 Optia Continuous Mononuclear Cell (CMNC) Collection.
 Document "Okay to Use" materials on the ABMT-COLL-019 FRM1 Optia CMNC Run Sheet.
- 8.1.3 After the collection of targeted plasma volume has been obtained, draw up 4,500 Units of heparin (1,000 unit/mL) and add it to the 750 mL bag of ACD using the "Okay to Use" materials.
- 8.1.4 Attach a **red** Medication Added Label with "Heparin 4,500 units to the 750 mL ACD bag".
- 8.1.5 Change the Anticoagulant ratio from 12:1 to 24:1 in the **Run Values** screen then adjust the inlet flow rate to the desired rate. Refer to ABMT-COLL-019 *Optia Continuous Mononuclear Cell (CMNC) Collection*.
- 8.1.6 Add 1,000 Units of heparin (1,000 units/mL) to the white blood cell (WBC) product collection bag by injection into the sterile barrier filter using the "Okay to Use" materials. The frangible inside the injection line above the sterile barrier filter must be broken to allow injection into the collection bag. Close the slide clamp when finished.
- 8.1.7 Remove 10 mLs from the ACD bag containing heparin and inject it into the WBC product collection bag after opening the slide clamp, through the sterile barrier filter. Close the slide clamp.
- 8.1.8 Place a **red** Medication Added Label with "Heparin/ACD 10 mLs + Heparin 1,000 units" to the WBC product collection bag label.
- 8.1.9 If patient is experiencing citrate toxicity during apheresis that is not relieved by intravenous (IV) or oral calcium, verify platelet count is adequate and refer to Section 8.1.3 and follow the outlined procedure.
- 8.1.10 Following **Rinseback**, verify "Okay to Use" materials are recorded on the ABMT-COLL-019 FRM1 *Optia CMNC Run Sheet*. Record final volume of cells and anticoagulant volume that the machine has added to the product on the WBC product collection bag label and the ABMT-COLL-019 FRM 1 *Optia CMNC Run Sheet*. The total volume of ACD should be approximately 10% of the cellular product volume.

9 RELATED DOCUMENTS/FORMS

- 9.1 ABMT-COLL-019 Optia Continuous Mononuclear Cell (CMNC) Collection
- 9.2 ABMT-COLL-019 FRM1 Optia CMNC Run Sheet

10 REFERENCES

10.1 Terumo BCT Spectra Optia Operator's Manual

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11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
05	M. Christen	Section 2 & 3: Clarified Introduction and Scope.
		Section 4: Defined acronyms throughout document.
		Section 8: Updated dose of heparin added to collection
		bag to current practice and use of 750 mL of ACD versus
		1,000 mL used previously.
		Section 8: Defined title of documents/SOPs.

Signature Manifest

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Name/Signature	Title	Date	Meaning/Reason
Mary Beth Christen (MC363	3)	04 Sep 2019, 10:52:00 AM	Approved

Management

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Name/Signature	Title	Date	Meaning/Reason
Jennifer Frith (JLF29)		04 Sep 2019, 12:58:11 PM	M Approved

Medical Director

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Nelson Chao (CHAO0002)		12 Sep 2019, 09:52:37 AM	Approved

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Document Release

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Betsy Jordan (BJ42)		13 Sep 2019, 01:43:47 PM	Approved