Research Protocol Proposal:

Title: A Single Blinded Randomized Control Trial Comparing the Use of ARISTA Polysaccharide Hemostat in Total Knee Arthroplasty (TKA)

Version: August 13, 2020

NCT05522153

Investigators:

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Purpose:

To determine if there is a benefit to overall reduction of blood loss, hematoma formation and outcomes in patients who undergo a primary unilateral TKA utilizing Arista MPH ® for hemostatic control.

Objectives:

The objectives of this study are to examine the effects of specific metrics in patients undergoing TKA with and without the utilization of Arista MPH® as a hemostatic adjunct.

These outcome metrics include direct comparison of:

- Blood loss (primary outcome)
- Transfusion rates (secondary outcome)
- Pre- and Post-operative thigh circumference
- Post-operative range of motion
- Adverse patient events within 90 days post-operatively

Number of Participants:

60 total patients (30 per group)

Methods:

Patients will be recruited from the Hospital for Special Surgery and Our Lady of Lourdes Programs. Patients will be prospectively enrolled when Institutional Review Board (IRB) approval is obtained. All patients will be undergoing a primary unilateral total knee arthroplasty for a diagnosis of osteoarthritis. Once enrolled in the study, each patient will be randomized into one of two groups. Group A will undergo a TKA utilizing Arista MPH ® intra-operatively. Group B will undergo a TKA without Arista MPH ®. All patients will receive a baseline IV dose of tranexamic acid per weight based guidelines prior to incision.

A thigh tourniquet will be utilized from prior to incision until wound closure is complete. Arista MPH ® will be used intra-operatively. A 5 gram vial of Arista MPH will be the standard of use. ARISTA will be used in accordance with the instructions for use. Additional need for Arista MPH ® usage during the case will be permitted and recorded. Standard electrocautory will be permitted, however additional thermal devices intended for hemostatic control will not be utilized.

Pre-operative hemoglobin, hematocrit, PT, PTT, and INR will be per standard institutional protocol within 30 days of surgery. The hemoglobin and hematocrit will be repeated 24 hours after the procedure per standard physician protocol. IV fluids administered pre-op, intra-op and post op for the first 24 hours will be recorded. Administration of any blood products from the time of incision until 90 days post-op will be recorded. Blood loss will be calculated via standard HSS. Drains will not be utilized.

The transfusion criteria is: a hemoglobin level of <8 g/dL or a hemoglobin level of <10 g/dL in a patient with symptomatic anemia or deemed at high risk because of notable underlying cardiac comorbidities. Blood will be administered 1 unit at a time, and the presence of symptoms or signs was reassessed.

Pre-operative thigh circumference will be measured on the day of the surgery. For standardization, the circumference will be recorded 15 cm proximal to the superior pole of the patella. Post-operatively the thigh circumference will be measured at 24 hours, post-operative day 14 +/- 4 days, and post operatively at 3 months +/- 1 week.

Post-operative knee range of motion will be recorded at 24 hours, post-operative day 14 +/- 4 days, and post-operatively at 3 months +/- 1 week.

Pre-operative and post-operative day 14 (+/- 4 days) and post-operative 3 months (+/- 1 week) knee society short form scores will be collected

All post-operative adverse events related to the procedure will be recorded. These invents include, but are not limited to: readmission, infection, prosthesis loosening, wound dehiscence, and wound drainage.

All data will be de-identified and securely maintained in an IRB approved manner.

Inclusion/Exclusion Criteria

Patients will be included if:

- They willingly desire to participate and signed the informed consent
- Are between the ages of 18 and 100 years of age
- Have the mental capacity to provide consent
- Are undergoing a primary unilateral total knee arthroplasty

Patients will be excluded from the study if any of the following exist:

- allergy to Arista MPH®
- allergy to tranexamic acid
- preoperative hepatic or renal dysfunction
- serious cardiac or respiratory disease including coronary artery stent placement
- congenital or acquired coagulopathy as evidence by INR > 1.4 or PTT > 1.4 times normal
- thrombocytopenia as identified by a preoperative platelet count of < 150,000/mm3
- history of thromboembolic disease
- pregnant or breast feeding
- donated preoperative autologous blood
- diagnosis of inflammatory arthritis
- a preoperative hemoglobin < 10 g/dL.

Study Results

TABLE 1: DEMOGRAPHIC DATA (ALL PATIENTS OVER COURSE OF STUDY)

Number of Subjects Screened	
Number of Patients Enrolled:	
Age	Average ± SD (Range)
Gender	Male:Female
Number of Withdrawn:	

Table 2: (ALL PATIENTS IN STUDY)

	PreOp	IntraOp	6Hrs
IV Fluids	Y/N	Y/N	Y/N
Hemoglobin	Average ± SD (Range)		Average ± SD (Range)

Hematocrit	Average ± SD (Range)		Average ± SD (Range)
Thigh circumference	Average ± SD (Range)		Average ± SD (Range)
KSS	Average ± SD (Range)		
PT	Average ± SD (Range)		
PTT	Average ± SD (Range)		
INR	Average ± SD (Range)		
Blood products administered?		Y/N (count)	Y/N (count)
Adverse Events		Y/N (count)	Y/N (count)

Table 5: Additional data elements for all patients in study.

	24hrs	48hrs	28 days	90days
IV Fluids	Y/N			
Hemoglobin	Average ± SD (Range)			
Hematocrit	Average ± SD (Range)			
Thigh Circumference	Average ± SD (Range)	Average ± SD (Range)		
Blood products administered?	Y/N (count)	Y/N (count)	Y/N (count)	Y/N (count)
Adverse Events	Y/N (count)	Y/N (count)	Y/N (count)	Y/N (count)

Attachment 9A

Interim Report

TABLE 1: DEMOGRAPHIC DATA (SINCE LAST REPORT "SLR")

Number of Subjects Screened SLR	
Number of Subjects enrolled SLR	
Age (SLR)	Average ± SD (Range)
Gender (SLR)	Male:Female
Number of Withdrawn: (SLR)	

TABLE 2: DEMOGRAPHIC DATA FOR ALL PATIENTS TO DATE

Number of Subjects Screened	
Number of Patients Enrolled:	
Age	Average ± SD (Range)
Gender	Male:Female
Number of Withdrawn:	