Help
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Study Identification Information

This is the first step in your Human Research Application. You will automatically be guided to the appropriate forms needed to complete your submission.

1.0 Title:

The Combination of Adductor Canal Block and Periarticular Injection with an Accelerated Rehabilitation Protocol. A novel technique for Patients Undergoing Total Knee Replacement (ACB PAI)

* Short Title for EPIC:

ACB PAI (If Not Applicable, please enter N/A)

2.0 Description:

3.0 * Principal Investigator:

Enrique Goytizolo, M.D.

4.0 Study Contact:

Phuong Dinh Mac

5.0 Co-Investigators:

First Name Last Name Organization
Michael Alexiades, M.D. Arthroplasty: Hip & Knee
Isabel Armendi Anesthesiology
Valeria Buschiazzo Anesthesiology
Jennifer Cheng Anesthesiology
Jodie Curren, RN Anesthesiology
Kara Fields Research
Rupali Joshi Rehabilitation
David Kim, MD Anesthesiology
Katherine Lee Anesthesiology
Yi Lin, MD Anesthesiology
Thuyvan Luu Anesthesiology
Phuong Dinh Mac Anesthesiology
Denesy Mancenido Anesthesiology
David Mayman, MD Arthroplasty: Hip & Knee
Iyabo Muse Anesthesiology

If a name does not appear in Co-Investigators directory, please contact zhouy@hss.edu to have an eCAP account created.

Date: Monday, August 22, 2016 8:29:18 AM Print Close
ID: 2014-018 Section: PART I - Study Identification Information
First Name Last Name Organization

Douglas Padgett, MD Arthroplasty: Hip & Knee
Amar Ranawat, MD Arthroplasty: Hip & Knee
Edwin Su, MD Arthroplasty: Hip & Knee
Matthew Titmuss Rehabilitation
Geoffrey Westrich, MD Arthroplasty: Hip & Knee
Jacques YaDeau, MD, PhD Anesthesiology
Angie Zhang Anesthesiology

6.0 Other Study Staff/Collaborators:

FirstName LastName Organization Email Role
There are no items to display

7.0 * Type of Application:

Clinical Research Proposal
Expedited Retrospective Chart Review
Request for Exemption
New Registry
Existing Approved Registry
Please click
here to preview
Exempt
Categories.
Click here to
preview Study
Designs.

8.0 Select appropriate funding sources for this study:

Name
Other

Other Funding Sources:

Anesthesiology Departmental Fund

Note: If the funding source of the study is 'Industry Funded Support' the Clinical Research Administration (CRA) will be notified.

If your study require CRA review, please upload applicable documents:
Name Version
There are no items to display
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CRP Information

1.0 The proposal should be submitted to the appropriate Clinical Review Panel (CRP) for scientific review. If you are unsure of which Clinical Review Panel to select, please contact Barbara Bosco at 212.606.1914

Date: Monday, August 22, 2016 8:29:18 AM Print Close
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*
Name
Anesthesiology
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Regulatory Status of Drugs and Devices

1.0 The regulatory status of the drugs or devices in this research proposal is:

Name

Approved for use by the FDA, but being studied in an “off-label” indication. Please note, in this case, an IND (Investigational New Drug) or IDE (Investigational Device Exemption) may be required from the FDA prior to use in a research study. If you have this information, please provide it below. If you do not have this information, or are uncertain about whether an IND or IDE is required, please contact Director of Clinical Research Administration at 212.774.7154, for assistance.

Help

Help

Drug/Device Details

1.0 If Drug:

Dexamethasone Sodium Phosphate

2.0 If Device:

Help

Help

Pharmacy Involvement / Impact to EPIC

1.0

Is this an inpatient study?

Yes No

2.0 * Will this study have Investigational Drug Service involvement? (Pharmacy will be purchasing/dispensing any medications being

used and/or study requires placebo and patient randomization)

Yes No

3.0

If the answer to either question is yes, please explain briefly below AND contact Mylinh Duong at 646.797.8410 (duongm@hss.edu) or Nicole Oliva at 646.797.8324 (OlivaN@hss.edu).

The study would benefit from having a specific CliniCIS/EPIC order set that indicates patient study enrollment. The study order will also include the following:
Reminder when writing Rehab orders
PT: DOS, TID for POD # 1 & 2 ONLY, as per SOC POD3 onwards
PT time slots: Between 8-12, 12-4, 4-7
No CPM

Help

Help

Study Locations

1.0 Select the Research Facilities where this study will be conducted:

Facility

HSS

1.1 If Other, please specify:

2.0 * Is this a multi-Center study?
No

ID: 2014-018 Section: PART II - Clinical Research Proposal - Nature of Study
This section will be reviewed by the appropriate Clinical Review Panel. Each of the headings in this section must be addressed.
Help
Specific Aims or Research Questions
1.0 What is the condition or intervention to be studied?
Total knee replacement is associated with severe post-operative pain. The purpose of this study is to compare two methods of treatment for pain control following Total Knee Replacement with an accelerated physical therapy protocol to aid the achievement of rehab milestones.
The two pain control methods include:
1-Perarticular injections during the surgery
2-Periarticular injections and adductor canal block
Please click
Here for
example.
2.0 What is/are the research question(s)/specific aim(s)? Pose very specific questions that can be addressed within the proposed design of the study. Prioritize them in order of importance.
Will the addition of an adductor canal block to peri-articular injections as an anesthetic regimen:
1. Allow for patients to achieve physical therapy discharge criteria earlier?
2. Reduce the pain NRS scores post-operatively?
3. Reduce the incidence of opioid related side effects?
3.0 What is/are the hypothesis(es)?
We hypothesize that performing an adductor canal block in addition to the periarticular injections will improve post-operative pain relief in patients receiving such an anesthetic regimen for TKA, allowing for a more rapid progression through PT. We hypothesize the reduction in pain in combination with the accelerated rehab protocol will aid the achievement of in-patient physical therapy milestones; more specifically, patients will meet the PT goal of negotiating stairs (via an accelerated PT regimen) 0.5 days earlier than patients who do not receive the adductor canal block.
We further hypothesize that by reducing pain, the patients receiving the adductor canal block in addition to the periarticular injections will consume less opioids and therefore will experience less opioid related side effects (nausea, vomiting, and pruritus). This will also assist progression with PT.
4.0 Identify and define the primary outcome and when the outcome will be measured. If measuring change in post-

ID: 2014-018 Section: PART II - Clinical Research Proposal - Nature of Study

operative function is the most important, that will be your primary outcome.

Our primary outcome is time when patient is able to meet physical therapy discharge criteria, indicated by the ability to independently negotiate stairs- nonreciprocal (one leg at a time), with or without rails, and with or without assistive device (walker or cane). The primary outcome will be assessed during the morning,afternoon, and evening PT sessions of DOS, POD 1 and POD 2. The ability for a patient to meet discharge criteria after POD 2 will be assessed once a day as part of the standard PT visit.

5.0 Identify and define the secondary outcome(s) and when they will be measured (list additional goals one at a time with their corresponding outcomes).

1) NRS Pain Scores – pre op in the holding area, upon spinal resolution, 24 and 48 hours after Anesthesia end time
2) Incidence of nausea, dizziness, and vomiting - upon spinal resolution, 24 and 48 hours after Anesthesia end time
3) Incidence of pruritus - upon spinal resolution, 24 and 48 hours after Anesthesia end time
4) Patient satisfaction - upon spinal resolution, 24 and 48 hours after Anesthesia end time
5) PainOUT - upon spinal resolution, 24 and 48 hours after Anesthesia end time
6) Opioid consumption -24 and 48 hours after Anesthesia end time. With type and amount.
7) Hospital length of stay
8) KSS scores – acquired through the Total Joint Registry at the surgeon's office visit pre-operatively and approximately 6 weeks post operatively

Length of hospital stay and opioidconsumption will be obtained from Clinicis after the patient is discharged from the hospital.

Help

Help

BACKGROUND - Be sure to answer each question individually

1.0 Explain why these research questions are being asked:

Several methods of controlling pain had been published in the literature including systemic narcotics, epidural analgesia, periarticular injections, femoral nerve block, sciatic nerve block, and lately the addition of adductor canal block. Several studies had been published using periarticular injections, comparing different methods of treatment with different primary outcomes. The

hypothesis of our study is that the addition of the ACB to the periarticular injection is going to decrease the pain, narcotic consumption and as a consequence improve rehabilitation leading to faster recovery and decrease the time to achieve the Physical Therapy criteria for discharge from the hospital.

Citations:

1. J. T. YaDeau, E. A. Goytizolo, D. E. Padgett, S. S. Liu, D. J. Mayman, A. S. Ranawat, M. C. Rade, G. H. Westric Bone Joint J VOL. 95B,

No. 5, MAY 2013
Analgesia after total knee replacement: local infiltration versus epidural combined with a femoral nerve blockade
2. Kelley TC, Adams MJ, Mulliken BD, Dalury DF.
J Arthroplasty 2013 Sep;28(8):12747.
Efficacy of multimodal perioperative analgesia protocol with periarticular medication injection in total knee arthroplasty: a randomized, doubleblinded study.
3. Nakai T, Tamaki M, Nakamura T, Nakai T, Onishi A, Hashimoto K
J Orthop 2013 Mar 17;10(2):924
Controlling pain after total knee arthroplasty using a multimodal protocol with local periarticular injections.
4. Yue DB, Wang BL, Liu KP, Guo WS
Chin Med (English) 2013 Oct;126(20):38515.
Efficacy of multimodal cocktail periarticular injection with or without steroid in total knee arthroplasty.
5. Jiang J, Teng Y, Fan Z, Khan MS, Cui Z, Xia Y J Arthroplasty 2013 Dec;28 (10):18827
The efficacy of periarticular multimodal drug injection for postoperative pain management in total knee or hip arthroplasty.
6. Lamplot JD1, Wagner ER1, Manning DW2
J Arthroplasty 2014 Feb;29(2):32934
Multimodal pain management in total knee arthroplasty: a prospective randomized controlled trial.
7. Ng FY, Ng JK, Chiu KY, Yan CH, Chan CW
J Arthroplasty 2012 Jun;27(6)

ID: 2014-018 Section: PART II - Clinical Research Proposal - Nature of Study
Multimodal periarticular injection vs continuous femoral nerve block after total knee arthroplasty: a prospective, crossover, randomized clinical trial.
8. Toftdahl et al Comparison of peri and intraarticular analgesia with femoral nerve block after total knee arthroplasty Acta Orthopaedica 2007; 78(2) 172179
9. Andersen et al A compression bandage improves local infiltration analgesia in total knee astrhroplasty Acta Orthopaedica 2008: 79 (6): 806-811
10. Kerr et al Local Infiltration Analgesia: a technique for the control of acute postoperative pain following knee and hip surgery Acta Orthopaedica 2008 79 (2): 174183
11. Busch CA, Shore BJ, Bhandari R, Ganapathy S, MacDonald SJ, Bourne RB, Rorabeck CH, McCalden RWJ Bone Joint Surg (Amer) 2006 May;88(5):95963.
Efficacy of periarticular multimodal drug injection in total knee arthroplasty. A randomized trial.
2.0 What is the background of the topic that you believe is important for the reviewer to know in considering this protocol, including prior studies by this research team. Describe strengths and deficiencies of prior studies; explain how this study fits in. Include references.
Finding an effective analgesic method that will help maintain quadriceps

muscle strength, will allow patients to tolerate physical therapy earlier and more efficiently. Adductor Canal Block (ACB) may be proposed to be an alternative nerve block since it does not further compromise quadriceps muscle strength in contrast to the traditional femoral block. This is especially significant in populations that may have weak quadriceps strength pre-surgery[1] and reduced quadriceps strength post op due to swelling[2].
Quadriceps muscle strength is significantly reduced after TKR, the reason for this is multifactorial. Swelling is a contributing factor[1]. Quadriceps strength is already reduced preop and further reduced by the surgery[2]. Finding an effective analgesic method that will help maintain quadriceps muscle strength, which is already compromised, will allow patients to tolerate physical therapy earlier and more efficiently. The adductor canal block (ACB) may be proposed to be an alternative to the traditional femoral nerve block.

ACB is predominately a sensory nerve block(3)**.**The adductor canal extends from the apex of the femoral triangle to the adductor hiatus.[4,5] The nerve branches of the adductor canal include the saphenous nerve, which innervates the infra patellar skin and the anterior knee capsule, and a nerve to the vastus medialis, which provides sensory innervation to the superomedial aspect of the

knee and the knee capsule[6]. When compared with the femoral nerve block, ACB has been shown to decrease pain and morphine use and preserve quadriceps strength post TKR. There were no episodes of falls associated with use of ACB which is an important finding to ensure patient safety [7,8]. On the contrary, studies have associated femoral nerve with risk of falling postoperatively [9,10,11].
ACB preserves quadriceps muscle strength better when compared to femoral nerve block. In a small study with volunteers, all subjects could be mobilized post ACB as compared to only 50% being mobilized with femoral nerve block[12]. A retrospective study of 298 patients undergoing TKA suggests that LIA is associated with early ambulation and improved pain control compared with lowdose continuous femoral nerve block. The addition of ACB was linked with additional increases in early ambulation, a more rapid shift to use of a standard low walker, and a higher occurrence of discharge to home instead of rehab[13]. In a randomized controlled pragmatic trial, we investigated whether local infiltration analgesia would result in earlier readiness for discharge from hospital after total knee replacement (TKR) than patient-controlled epidural analgesia (PCEA) plus femoral nerve block. The results demonstrated no difference between the groups. We also found that the pain scores at rest and with movement on the periarticular group were NRS 3-4 and had a wide range of variability (please see below table)[14].
Complications involving injury to the infrapatellar branch of the saphenous nerve for patients receiving ACB for TKA were discussed in a previous study, but those complications were acknowledged as known complications for the surgical procedure[15]. In relation to this prospective study, we believe that the addition of the adductor canal block to the periarticular injection will facilitate accomplishment of rehabilitation goals and decrease the pain scores even further.
References
1. Mizner RL, Petterson SC, Stevens JE, Vandenborne K, Snyder-Mackler L. Early quadriceps strength loss after total knee arthroplasty. The contributions of muscle atrophy and failure of voluntary muscle activation. J Bone Joint Surg Am . 2005;87: 1047–1053.

2. Holm B, Kristensen MT, Bencke J, Husted H, Kehlet H, Bandholm T. Loss of knee-extension strength is related to knee swelling after total knee arthroplasty. Arch Phys Med Rehabil . 2010;91:1770–1776.
3. Lund J, Jenstrup MT, Jaeger P, Sorensen AM, Dahl JB. Continuous adductorcanal-blockade for adjuvant post-operative analgesia after major knee surgery: preliminary results. Acta Anaesthesiol Scand . 2011;55:14–19.
4. Manickam B., Perlas A., Duggan E., Chan VW, Ramlogan R. Feasibility and efficacy of ultrasound-guided block of the saphenous nerve in the adductor canal. Reg Anesth Pain Med . 2009;34:578–580.
5. Tubbs RS, Loukas M, Shoja MM, Apaydin N, Oakes WJ, Salter EG. Anatomy and potential clinical significance of the vastoadductor membrane. Surg Radiol Anat . 2007;29:569–573.
6. Horner G., Dellon AL. Innervation of the human knee joint and implications for surgery. Clin Orthop Relat Res . 1994;301:221–226.

7. Jenstrup MT, Jaeger P, Lund J, et al. Effects of adductor-canal-blockade on pain and ambulation after total knee arthroplasty: a randomized study. Acta Anaesthesiol Scand . 2012;56:357–364.
8. Jaeger P, Grevstad U, Henningsen MH, Gottschau B, Mathiesen O, Dahl JB. Effect of adductor-canal-blockade on established, severe post-operative pain after total knee arthroplasty: a randomised study. Acta Anaesthesiol Scand . 2012;56:1013–1019.
9. Ilfeld BM, Duke KB, Donohue MC. The association between lower extremity continuous peripheral nerve blocks and patient falls after knee and hip arthroplasty. Anesth Analg . 2010;111:1552–1554.
10. Johnson RL, Kopp SL, Hebl JR, Erwin PJ, Mantilla CB. Falls and major orthopaedic surgery with peripheral nerve blockade: a systematic review and meta-analysis. Br J Anaesth . 2013;110:518–528.
11. Muraskin SI, Conrad B, Zheng N, Morey TE, Enneking FK. Falls associated with lower-extremity-nerve blocks: a pilot investigation of mechanisms. Reg Anesth Pain Med . 2007;32:67–72.
12. Jaeger P, Nielsen ZJ, Henningsen MH, Hilsted KL, Mathiesen O, Dahl JB. Adductor canal block versus femoral nerve block and quadriceps strength: a randomized, double-blind, placebo-controlled, crossover study in healthy volunteers. Anesthesiology. 2013 Feb;118 (2):409-15.
13. Perlas A, Kirkham KR, Billing R, Tse C, Brull R, Gandhi R, Chan VW. The impact of analgesic modality on early ambulation following total knee arthroplasty. Reg Anesth Pain Med. 2013 Jul-Aug;38 (4):334-9.
14. YaDeau JT, Goytizolo EA, Padgett DE, Liu SS, Mayman DJ, Ranawat AS, et al. Analgesia after total knee replacement: local infiltration versus epidural combined with a femoral nerve blockade: A prospective, randomised pragmatic trial. Bone Joint J 2013; 95-B: 629–35.
15. Henningsen MH, Jaeger P, Hilsted KL, Dahl JB. Prevalence of saphenous nerve injury after adductor-canal-blockade in patients receiving total knee arthroplasty. Acta Anaesthesiol Scand. 2013 Jan;57(1):112-

3.0 Identify specific gaps in current knowledge that this study is intended to fill.

This project would investigate the effectiveness of this particular anesthetic combination through patients' readiness for discharge by physical therapy, in addition to other

secondary markers, i.e. pain scores, as a gauge. In addition, this study would also introduce a new PT regimen and allow patients to receive two physical therapy visits instead of one, providing the opportunity for a faster progression through rehab milestones and therefore the ability to achieve PT discharge criteria.

ID: 2014-018 Section: PART II - Clinical Research Proposal - Nature of Study

4.0 How will answering these questions change clinical practice, change concepts about the topic or confirm the work of other investigators?

If the peri-articular injection plus adductor canal block regimen improves time to readiness to PT discharge, and lowers pain scores then it could change current practice guidelines. Reducing the pain after surgery will have an enormous implication, including the improvement of patient satisfaction, decrease in morbidity, decrease in length of hospital stay, and the possibilities for further research.

In regards to the accelerated rehab protocol, if there is an improvement in time to readiness to PT discharge then there could be a change in rehab clinical practice.

5.0 Is this a pilot study that could lead to a more definitive protocol or different study? Yes No

5.1 If you answered No, please explain below:

This is not a pilot study. It is part of an ongoing series of studies that seek to improve postoperative pain in total knee replacement patients. We anticipate that there will be future studies, potentially based on this study.

6.0 Please upload reference or additional document here (if needed).

Name Description

There are no items to display

Help

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Study Design

1.0

Observational:

Name Description

There are no items to display

2.0

Experimental:

Name Description

Randomized

Controlled

Clinical Trial

This is the “gold standard” for clinical research. These prospective studies have at least two groups. Patients meeting strict inclusion/exclusion criteria are enrolled and randomly assigned to receive either an experimental intervention or to receive what is considered to be an acceptable alternative –

ID: 2014-018 Section: PART II - Clinical Research Proposal - Nature of Study
Name Description
usually the current standard of care or a placebo (e.g., study of hylauronic acid injection versus cortisone for arthritis).

2.1 If Other, please specify:
N/A

2.2 If Randomized Controlled Clinical Trial is selected, please choose one of the following:
Name
Other

If other, please list name or indicate N/A below:
Anesthetic Regimen:

Group 1- Periarticular Injection only group
Group 2- Periarticular Injection + Adductor Canal Block group

ID: 2014-018 Section: PART II - Clinical Research Proposal - Recruitment & Enrollment
Help

Recruitment

1.0
Check all that apply to describe your study population:
Population
Patients
Vulnerable Populations
There are no items to display

1.1 If Other, please specify:
N/A

2.0 Inclusion Criteria: list characteristics that potential subjects and controls need to have. Use a bullet format, if applicable.
_ Patients with osteoarthritis scheduled for primary tricompartmental total knee arthroplasty with a participating surgeon and anesthesiologist
_ Age 18 to 80 years
_ Planned use of regional anesthesia
_ Ability to follow study protocol

ID: 2014-018 Section: PART II - Clinical Research Proposal - Recruitment & Enrollment
_ English speaking (secondary outcomes include questionnaires validated in English only)

3.0
Exclusion Criteria: list characteristics that would cause you to exclude potential subjects and controls.
Justify any age, ethnicity, language, or gender-based exclusion criteria. Use a bullet format, if applicable.
Hepatic or renal insufficiency
Patients younger than 18 years old and older than 80
Patients intending to receive general anesthesia

Patients planning to go to rehab post operatively
Patients scheduled to go into the OR after the time agreed upon by Physical Therapist*
Allergy or intolerance to one of the study medications
Patients with an ASA of IV
Chronic gabapentin/pregabalin use (regular use for longer than 3 months)
Chronic opioid use (taking opioids for longer than 3 months)
Diabetes
Patients on workers compensation or disability
*Patients whose spinals are unlikely to resolve by 7:00 pm will be excluded from the study because it is not standard of care for physical therapists to see patients past 7:00 pm on the day of surgery.

4.0 Age Range:

18-80

5.0 Describe how you will identify and recruit potential subjects for participation in the study.

Following discussion of the study with the surgeon, the investigator in the holding area before the surgery will approach the patient. The patient will be given a description of the research project. Informed consent will be obtained by an attending anesthesiologist co-investigator prior to participation.

6.0 * Please select enrollment type from following drop down list:

Over Course of Study

ID: 2014-018 Section: PART II - Clinical Research Proposal - Recruitment & Enrollment

Help

Help

Patients

1.0 Please check the box(es) below that best reflect how patients will be identifed and recruited for participation.

How subjects will be identified

- Potential subjects will be identified after a review of medical records of patients under the care of one or more of the study investigators
- Medical records and/or other Institution sources (databases,registries,billing records,pathology reports,admission logs) will be reviewed to identify potential participants. May involve access of records by individuals not involved in the patient's care.

Potential subjects will be identified by their treating physicians and referred to the researchers. Patients' private and identifiable information will not be shared prior to receiving permission from the patient to do so.
Potential subjects will be identified from a registry of individuals interested in research opportunities.
Subjects will roll-over from another research study.
Potential subjects will self-refer in response to advertisements.

Help

Target Enrollment

1.0 * What is the maximum number of subject you plan to enroll in this study at HSS?(Please enter a number)

2.0 If this is a multi-center study, indicate the projected total subject accrual across all sites.
Help
ID: 2014-018 Section: PART II - Clinical Research Proposal - Interventions or Observations
Help
Interventions and Observations
1.0
Be specific and describe the Interventions or Observations that will be part of this research project. Include a detailed description of the treatment arms, if applicable.

ID: 2014-018 Section: PART II - Clinical Research Proposal - Interventions or Observations
Pre-Operative:
Both groups will received preoperative meloxicam (7.5mg PO if age 75 or older; 15 mg otherwise) + extended release oxycodone (10 mg PO). Patients will provide NRS pain scores as well.
Intraoperative:
Group 1- Periarticular only group
A spinal anesthetic with 0.5% bupivacaine (10 or 12.5) will be performed. The surgeon will perform the periarticular injections; one deep injection prior to cementation and then a second more superficial injection prior to closure. The deep injection will consist of bupivacaine 0.5% with epinephrine, 30cc; morphine, 8 mg/ml, 1 cc; methylprednisolone, 40 mg/ml, 1 ml; cefazolin, 500 mg in 10 ml; normal saline, 22cc. The superficial injection will be 20 ml 0.25% bupivacaine. Both groups will receive intraoperative intravenous sedation with midazolam and propofol. Patients will not be given intravenous opioids or ketamine during the operation. Patients will be given 2 mg of intravenous Dexamethasone. Patients will be given 4 mg Ondansetron and 20 mg Famotidine.
Group 2- Periarticular + ACB group
A spinal anesthetic with 0.5% bupivacaine (10 or 12.5) will be performed. Then the adductor canal block* technique will be performed; supine position, after IV sedation. Ultrasound guided with linear transducer 8 MHz. Chiba needle, 22 G / 4 inches. The femoral artery will be identified in the adductor canal deep to the Sartorius muscle. The block will consist of 15 cc of Bupivacaine 0.25% with 2 mg of Preservative free Dexamethasone. The local anesthetic will be delivered periarterial between 12 and 6 o'clock. The surgeon will perform the periarticular injections; one deep injection prior to cementation and then a second more superficial injection prior to closure. The deep injection will consist of bupivacaine 0.5% with epinephrine, 30cc; morphine, 8 mg/ml, 1 cc; methylprednisolone, 40 mg/ml, 1 ml; cefazolin, 500 mg in 10 ml; normal saline, 22cc. The superficial injection will be 20 ml 0.25% bupivacaine. Patients will not be given intravenous opioids or ketamine during the operation. Patients will be given 4 mg Ondansetron and 20 mg Famotidine.
*The block function will be assessed and recorded by the Anesthesiologist postoperatively. The assessment of the adductor canal block will be done in the Recovery room after the resolution of the spinal anesthesia. We will use a alcohol swab to test the cold sensation first on the non operated leg and then on the operated one. The test will be performed at the level of the medial maleoli of

the tibia. If the patient has sensation or no sensation it will be recorded as Block NOT working or Block working, respectively. The same procedures will be followed for the peri-articular injection only group, so as to not unblind participating patients.
Postoperative:

ID: 2014-018 Section: PART II - Clinical Research Proposal - Interventions or Observations
Analgesia:
Postoperative analgesia will consist of: acetaminophen(10mg IV 1 hour post PACU admission), dexamethasone (10mg IV 1 hours post PACU admission), oxycodone (5 mg q 3 hr PRN), acetaminophen (1 g PO q 8 hr), ketorolac (15-30 mg IV q 6 hr X 4 doses), meloxicam daily (7.5mg PO if age 75 or older; 15 mg otherwise, to start after ketorolac is finished), dilauded (0.5 mg IV q 5 min X 4 PRN). In cases of severe pain (NRS scores greater than 6 for >2 hours), salvage therapy will be available using intravenous hydromorphone PCA. Orders for ondansetron (4 mg IV q 8 hr PRN) and metoclopramide (10 mg IV q 6 hr PRN) will also be placed, in case patients experience nausea.
Rehabilitation:
Patients participating in the study will have an accelerated rehab regimen until they meet Rehab goals for discharge. They will be seen by a physical therapist once on the day of surgery and then three times by a physical therapist (until they meet Rehab goals) on post operative day 1 and 2. If physical therapy (PT) discharge criteria are not met before POD 3, patients will default to the standard PT protocol (1 PT session + 1 Mobility technician session).
REHAB PROTOCOL:
1. Ambulation: WB: WBAT; walker, progress as appropriate; Day of Surgery-OOB to ambulate
2. TID PT
3. NO CPM
4. Jordan Splint: NO ORDER FOR JORDAN SPLINT
5. Cryotherapy: ICE BAGS ONLY
6. TED stockings FOR HOME USE
7. VENO DYNES for INHOUSE
8. NO DRAINS
9. Negotiate stairs with one rail + cane or two rails.
10. Patients can be cleared when independent on a walker OR cane.
Straight leg test (SLR):
• Tested with patient in supine with non-operated leg in knee flexion, patient is asked to perform a quad set (isometric quadriceps contraction) and while maintaining the contraction simultaneously lift operated left straight up to 45 degrees (hip flexion) or ~ six inches from the floor/bed.
• Test is considered to be positive if patient is able to perform SLR without extension lag (leg below knee unable to hold while performing SLR).
• Negative SLR is indicative of poor quadriceps control.
Research Staff:

1) DOS, upon spinal resolution: NRS pain scores, painOUT
2) POD 1, 24-h post-anesthesia end: NRS pain scores, painOUT, Hospital DC lag questionnaire
3) POD 2, 48-h post-anesthesia end: NRS pain scores, painOUT, Hospital DC lag questionnaire

2.0 Will you be collecting human fluid or tissue? Yes No

If yes, what will you be collecting? Fluid Tissue

(Intraoperative and/or outpatient collection)

Help

Help

Data Collection

1.0 Indicate what data will be collected.

Data will be collected by a research staff member or a co-investigator. Please see the data collection sheets for further detail.

1. Day of Surgery in the holding area - patient demographics (name, age, sex, race, BMI); NRS pain score at rest, during ambulation, while bending knee
2. Day of Surgery upon spinal resolution - Procedure length; ASA classification; tourniquiet timel; NRS pain score at rest, during ambulation, while bending knee; painOUT; opioid consumption; PT data sheet (assessing lines, nausea, vomiting, dizziness, pain NRS post-PT, buckling, transfer details, ambulation details, stair details, straight leg raise)
3.POD 1 - NRS pain score at rest, during ambulation, while bending knee; painOUT; opioid consumption; PT data in the morning, afternoon, and evening (assessing lines, nausea, vomiting, dizziness, pain NRS post-PT, buckling, transfer details, ambulation details, stair details, straight leg raise; was discharge criteria met (time and date)?); Hospital DC lag questionnaire
4.POD 2 - NRS pain score at rest, during ambulation, while bending knee; painOUT; opioid consumption; PT data in themorning, afternoon, and evening (assessing lines, nausea, vomiting, dizziness, pain NRS post-PT, buckling, transfer details, ambulation details, stair details, straight leg raise; was discharge criteria met (time and date)?); Hospital DC lag questionnaire
5. Knee Society Score - Both pre-operatively and at first post operative surgeon's office visit (obtained through Total Joint Registry)

2.0 Who will collect the data:

Enrique Goytizolo, M.D.
Jacques YaDeau, MD, PhD IRB Vice Chair

Angie Zhang Research Assistant
Rupali Joshi Physical Therapist
Isabel Armendi
David Kim, MD
Thuyvan Luu
Jodie Curren, RN
Denesy Mancenido Assistant Director, Research
Yi Lin, MD
Matthew Titmuss Physical Therapist

Jennifer Cheng Research Associate
Valeria Buschiazzo
Phuong Dinh Mac
Katherine Lee
Iyabo Muse Regional Anesthesia fellow

3.0 When the data will be collected? Include timing of visits(either SOC or specifically for the study).

During the patients' hospital stay and visits to surgeons offices

4.0

From what source:

Medical Records
Patient
No Private Office Charts Please specify which private office:
Yes Registries Please specify which registry: Total Joint
Other Please specify:

Help
Help

General Methods and Procedures

1.0 * Are controls included in the study? Yes

1.1 If yes, describe how they will be matched with the study subjects; state whether the controls will have identical data recorded, or describe any differences compared to the intervention subjects.

This is a randomized controlled trial. All patients will have identical data recorded. Anesthesia, analgesia, and rehabilitation plans will be identical among groups, except for the intervention described above (Intervention Section - adductor canal block).The control group will receive the periarticular injections and the investigational group will receive the periarticular injections and an adductor canal block.

ID: 2014-018 Section: PART II - Clinical Research Proposal - Interventions or Observations

2.0 * Are all tests Standard of care? No

If not, identify which tests are not standard of care. What source of funds will be used to pay for them (text box below):

3.0 * Will surveys/questionnaires be used? Yes

4.0 * Does the study involve randomization? Yes

5.0 * Does your study included Placebo or No-Treatment Arm? No

6.0 * Does your study included Washout of Previous Medication?

No

7.0 Data collection sheet should be created for the study and uploaded:

Name Version
Checklist for Anesthesiologist - ACB PAI.doc 0.01
GoytizoloACBPAI IRB2014018 UNSTAMPED.pdf 0.01

Help
Help

Surveys & Questionnaires

1.0 Please add all survey instruments and questionnaires to be used in this study:

Name
Standard
Instument
Upload Instrument Usage of Instrument
View painOUTyes
painOUT
Questionnaire(0.01)
This instrument will be used to acquire secondary outcome data.
Help

Randomization

1.0 Please state who will do the Randomization:

A research assistant not otherwise involved with the study will prepare a randomization table. Group assignment will be indicated on cards within numbered sealed opaque envelopes. After consent is obtained, the envelope will be opened in the operating room, not in the presence of the investigators who plan to assess the patients postoperatively.

ID: 2014-018 Section: PART II - Clinical Research Proposal - Interventions or Observations

2.0 Please state when the Randomization will be done:

The randomization will occur once IRB approval has been obtained and prior to the start of study enrollment. Randomization has been generated via computer randomizer. Randomization will be revealed after the patient gives consent and it is obtained in the holding area prior to surgery. At the time consent is obtained the anesthesiologist will be given a sealed opaque envelope corresponding to the patients study id number and randomization to either treatment or control.

3.0 Please state how the Randomization will be performed:

A research assistant not otherwise involved with the study will prepare a randomization table using randomizer software.

4.0 Please state who will insure that the Randomization is carried out and if anyone will be blinded to the Randomization group:

The Research Manager will ensure that the randomization is carried out. The physical therapist, nursing, PA, pain team, research staff, as well as the study patient will be unaware of which interventional group the study patient is in.

Help

ID: 2014-018 Section: PART II - Clinical Research Proposal - Sample Size & Data Analysis

Help

Sample Size and Data Analysis

If you are uncertain about how to calculate your sample size and determine appropriate data analysis, please contact the Epidemiology and Biostatistics Core at biostats@hss.edu
for assistance in completing this section.

1.0
Is this is a case series based only on the patients available using descriptive statistics in lieu of a sample size calculation?
* No
Help
Help
Sample Size and Data Analysis
Support estimates with evidence from the literature of prior studies and perform an appropriate sample size calculation.

ID: 2014-018 Section: PART II - Clinical Research Proposal - Sample Size & Data Analysis
For hypothesis testing (e.g., the calculation of p-values using statistical tests), you need to estimate your available sample size and calculate the effect size that will be detectable using your proposed statistical analysis plan. This also applies to a case series where you plan hypothesis testing.
1.0 If you have consulted with a statistician, please indicate their name:
Kara Fields
2.0 Proposed sample size analysis, include the following:
- Student's t-test, ANOVA, chi-square, regression, etc;
- Alpha level;
- Beta or power level;
- Primary outcome variable estimate (mean +/-s.d. for continuous outcome, frequency/percentage for categorical variable);
- Number of groups being compared (use 1 for paired analysis within the same subjects);
- Effect size or change expected between groups;
- Resulting number per group

A previous trial at HSS found the standard deviation (SD) in time until ready for discharge (based on achievement of PCA, nausea, diet, urination, pain, surgical, medical, and PT criteria) for TKR patients receiving periarticular injections to be 0.83 days (YaDeau, 2013). This SD was considered to be a reasonable estimate of the variability in the time until patient is able to independently negotiate stairs within the periarticular injection alone group. A 0.5 day difference in mean time until patient is able to independently negotiate stairs between the periarticular injection alone and periarticular injection + ACB groups was determined to be clinically meaningful. With two-sided alpha set at 0.05, power at 0.8, and the addition of 10% more patients to account for potential protocol violations, the number of patients required for a two-sample t-test is 53 patients per group (106 patients total*).

*Our a priori sample size calculation assumed that 96 of 106 enrolled patients would adhere to trial protocol. However, ultimately only 92 out of 106 patients adhered to trial protocol. Therefore, we plan to continue enrollment up to 114

patients until 96 patients without protocol deviations are enrolled.
3.0
Data Analysis: describe how the primary outcome will be analyzed and what types of statistical calculations will be used. Do the same for each secondary outcome. Reiterate briefly the main analysis to be done, which groups, which variables, possible confounders. Address how possible confounders will be identified and handled in analysis:

ID: 2014-018 Section: PART II - Clinical Research Proposal - Sample Size & Data Analysis
The primary outcome, time until the patient is able to independently negotiate stairs, will be compared between the periarticular injection alone and periarticular injection + ACB groups with a two-sample t-test or Wilcoxon rank-sum test, depending upon the distribution of the data. The precision of the estimate of the difference between groups will either be reported as a 95% confidence interval for the difference in means or the Hodges-Lehmann estimate of location shift.
Longitudinal secondary outcome data (NRS pain scores, narcotic consumption, incidence of side effects, painOUT score, and patient satisfaction) will be compared between groups via the generalized estimating equations (GEE) approach.
Change in KSS, and hospital length of stay will be compared between groups with two-sample t-tests or Wilcoxon rank-sum tests, depending upon the distribution of the data.
The success of blinding in each arm will be assessed with the Bang Blinding Index' (Bang H, Flaherty SP, Kolahi J, Park J. Blinding assessment in clinical trials: A review of statistical methods and a proposal of blinding assessment protocol. Clin Res Regul Aff 2010; 27:42-51.)
Help
Help

Consent Information

1.0 Describe how, when, and where the consent process will be initiated:
A MD co-investigator will obtain consent from the patient in the holding area prior to entering the operating room on the day of surgery. That physician will also serve as that patient's anesthesiologist.
2.0 Who will obtain informed consent from subjects for this research?
First Name Middle Name Last Name Title
Enrique Goytizolo, M.D.
Jacques YaDeau, MD, PhD IRB Vice Chair
Edwin Su, MD
Amar Ranawat, MD
Douglas Padgett, MD
David Kim, MD
Michael M Alexiades, M.D. MD
David Mayman, MD
Yi Lin, MD
Geoffrey Westrich, MD
Iyabo Muse Regional Anesthesia fellow
Help

Help
IRB Application

1.0 Please provide lay abstract:
The purpose of this study is to compare two methods of treatment for pain control following Total Knee Replacement with an accelerated physical therapy protocol to aid the achievement of rehab milestones. The two pain control methods include: 1-Perarticular injections during the surgery and 2-Periarticular injections and adductor canal block. The primary outcome is time when patient is able to meet physical therapy discharge criteria, indicated by the ability to independently negotiate stairs.
2.0 * Requested Review Type:
Expedited
3.0 Ancillary/Impacted Services Review (select all that apply):
Note: Do not confuse the committees below with CRP or Research Service Chief
Ancillary Committees
Nursing
Pharmacy
Rehabilitation
4.0 * Is Genetic Testing involved in this study? No
Help
Expedited Qualification
If you check any of the items below, the study is qualified for EXPEDITED review status under federal guidlines.
1.0 * Select all that apply:
Question
•
1. Clinical studies of drugs and medical devices only when: (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review). OR (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2. This research involves only the collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from healthy, non-pregnant adults or children where the amount of blood and frequency does not exceed federal regulations for normal clinical care.
3. This research involves prospective collection of biological specimens for research purposes by noninvasive means.

Question
4. This research involves the collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.
5. This research involves materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes.
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. This research will be performed on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or will employ a survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
8. This research involves Continuing Review of study previously approved by the convened IRB
9. This research involves Continuing Review of study which are not conducted under an investigational new drug application or investigational device exemption where categories two through eight do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.
Help

Assessment of Research Procedures

1.0 Describe any potential for direct benefits to participants in this study:

Patients may experience a longer duration of pain relief. If this is the case, pain and opioid consumption would be reduced. This could reduce the incidence of opioid related side effects and increase patient satisfaction. Study participants will also be visited by a physical therapist twice a day and a mobility technician once a day on post operative day 1 and 2, providing an additional physical therapist visit when compared to the standard of care (1 physical therapist visit and 1 mobility technician visit per day). The accelerated physical therapy protocol may allow patients to meet physical therapy discharge criteria earlier and potentially be discharged from the hospital earlier than they would had they not been participating in the study.

2.0 Describe any potential benefits to society:

Better pain control for total knee replacement would benefit society. If the combination of investigational anesthetic regimen along with It would allow patients to achieve rehabilitation milestones earlier than average, clinical practice could be influenced.
Help

Minimal Risk

https://ecap.hss.edu/eCAP/ResourceAdministration/Project/PrintSmartForms?Project=com.w... 8/22/16
ID: 2014-018 Section: PART III - IRB Application - Submission Summary

The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. This includes, but is not limited to, administration of non-invasive data collection measures, collection of blood samples, collection of existing data and observational studies

1.0

Please select the applicable tests with standard wording for risks from the list below:

Name Description

There are no items to display

Risk of breach of confidentiality, include the following:

[ADDRESS THE RISK TO PATIENT PRIVACY, AS APPROPRIATE BASED ON THE SPECIFIC INFORMATION BEING KEPT IN THE REGISTRY – FOR EXAMPLE, “Participation in this research involves the potential risk of a breach of confidentiality of your health information that is stored. HSS tries to minimize those risks by (i) removing some direct identifiers from information stored [(i.e., names, social security numbers, medical record numbers)][MODIFY AS NECESSARY]; (ii) securing, in a separate location, and limiting access to information linking codes (i.e., linkage codes) assigned to the registry information with direct participant identifiers; and (iii) limiting access to information stored to HSS investigators.”]

2.0 * Is any physical testing being done other than surveys, questionnaires, etc?:

No

2.1 If yes, please list the testing being done and describe any potential risks:

Help

ID: 2014-018 Section: PART III - IRB Application - Assessment Procedures

Help

Informed Consent

1.0 Indicate the types of consent that will be involved in this study (check any or all that apply):

Informed Consent Category

Written/signed consent by subject

2.0 Waivers: If you are applying for any waivers of consent (check any or all that apply):

Name

Waiver of Consent

Waiver of Assent

Waiver of Parental Permission

ID: 2014-018 Section: PART III - IRB Application - Assessment Procedures

Name

Waiver of Written or Signed Consent (i.e. information sheets, telephone consent, verbal script)

3.0 * Will this study include non-english speaking participants?

No

4.0 If the study does not include non-english speaking participants, please justify:

This study utilizes questionnaires that are validated in english. Therefore only english speaking patients will be recruited for study participation.

5.0

Please provide assurance by checking the box below that the study will make all possible efforts to collect Federally mandated gender, race and ethnicity data for all subjects included in the study.

- Agree

This will not be possible for the following reasons:

6.0 Will this study be posted at ClinicalTrials.gov?

Yes No

If yes, please post at the site upon approval of the study by the IRB. ClinicalTrials.gov requires that listings be updated every 12 months as well as 30 days after Major Amendment approvals of a protocol. For more information about what studies should be posted at the site and when to update a posted study at the site, please visit the following website:

http://www.icmje.org/faq_clinical.html

Help

Consent Forms & Process of Consent

1.0

Good News! We've prepared several different types of consent form templates with some of the information you have already provided. Please follow the instructions below to complete the process.

Instructions:

1.1) Download the applicable consent form(s) to your machine and modify as appropriate. Save the modified documents and upload them in the following question.

Assent Form For Adolescent Participation In Research Study

Lay term

Glossary

ID: 2014-018 Section: PART III - IRB Application - Assessment Procedures

Informed Consent To Participate In A Genetic Research Study

Informed Consent To Participate In Research

Informed Consent To Participate In Research Registry

1.2) Please upload all informed consents, waivers, translated documents, phone recruitment scripts, recruitment ads, brochures, etc to be used in this study.

Name Modified Version

Updated Consent form 7/12/2016 1:44 PM 0.01

Help

Data Privacy & Confidentiality

1.0 How will the data for this study be collected and recorded?

Data will be collected by an investigator or research assistant. Sources of data include medical records and patient physical assessments/interviews conducted by study personnel. Data will be recorded and managed using REDCap electronic data capture tools hosted at the Clinical and Translational Science Center (CTSC) at Weill Cornell Medical College. REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies, providing: 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources. Connection to REDCap occurs via the hospital's encrypted cable and wireless networks, and data will be entered through a password-protected computer terminal or iPad.

2.0 Select Data Recording Identifiers used on this study:

Name
De-identified
Coded (Data will be linked to subjects via encrypted codes)
Identifiable

2.1 If Other is selected, please specify:

ID: 2014-018 Section: PART III - IRB Application - Assessment Procedures

N/A

3.0 Where will the research data be stored? Please specify the physical location and how it will be secured to protect confidentiality:

Any information collected electronically will be stored on the REDCap server. The REDCap server and data are hosted by Weill Cornell Medical College CTSC, with the servers physically located in the Payson building of Weill Cornell New York Presbyterian Hospital. Access to this space is limited to members of the Hospital's informatics department. Electronically, several intrusion protection mechanisms, including firewalls and encryption, are in place to protect the server and its data.

Any paper-based data sheets utilized for the study will be stripped of all personal identifiers whenever possible and stored the department's locked office.

4.0 Who, other than the specified study team, will have access to the study records or data? Specify their name, role, and affiliation.

Informatics staff in the Weill Cornell Medical College CTSC will have access to the REDCap server as needed for administrative purposes. HSS IRB members, upon request, may also review study records and/or data.

Do not list study

personnel
already listed in
Section 1:
5.0 If coded or identified data will be released, specify the persons/agencies to whom the information will be released. Please also indicate the provisions that will be taken to assure that the transmission of the data will maintain confidentiality:
Data will be released to the project's statistician, at designated intervals, including interim analysis (if appropriate) and at end of study. Any identifiers not essential for data analysis will be removed from the data set, which will be sent to the statistician as a password protected, encrypted file.
6.0 Describe what will happen to the data or data set when the study is completed. Please indicate your plans for the

destruction of identifiers at the earliest opportunity consistent with the conduct of the research and/or clinical needs, if applicable:
After data analysis, the study data set will be stored as an Excel or SPSS file. A unique feature of REDCap is that data fields marked as protected health information (PHI) can be automatically de-identified when data is exported. We will utilize this option when closing out the study after data analysis, so that no identifiers remain in the stored Excel or SPSS data set. In the REDCap program, the study will be changed from production mode to archive mode. This means the data and study forms will no longer be accessible to REDCap users. Only the research assistant and research manager will have rights to unarchive the study. The study will be maintained in REDCap for the period of time required by hospital/federal regulations, at which point it will be deleted.
7.0
If audio/video recordings or photographs will be used, specify your plans for deidentifying or anonymizing the material and when it will be destroyed:
No audio/video recordings, photographs or medical imaging will be used in this study.
8.0 Describe the data management software that will be used. Identify who will enter the data, and what data quality control measures will be used, such as dual entry, validation checks and locked fields. Insure that your plans are consistent with HIPAA regulations. Contact Ms. Andrea Ansorge with any questions related to HIPAA regulations and research.

Data will be collected, managed, and stored using REDCap. Information will be entered directly into REDCap by a research assistant or other study personnel. Data quality assurance will include systematic training for study staff about patient assessment, administration of standardized surveys/questionnaires, and abstracting data from patient charts and medical systems. REDCap also features auto-validation in designated fields, the ability to create calculated fields, and provides audit trails for tracking data manipulation and user activity.

ID: 2014-018 Section: PART III - IRB Application - Assessment Procedures

9.0 Describe the measures that will be used to preserve confidentiality and rights of subjects.

Below is Hospital for Special Surgery standard accepted practice. By completing this information, you attest that you will follow this procedure for preserving the confidentiality and rights of the subject. You can use the following standard, approved statement.

9.1 If the HSS statement does not apply, please revise it accordingly.

Access to the REDCap program is password-protected, and access to a specific study's information within the program is limited to the research assistant and other IRB-approved study personnel who have been given permission to view and/or enter study data. REDCap program access is authorized by the CTSC; particular study access is granted by the research assistant. For data exports, fields marked as protected health information (PHI) in REDCap will be de-identified, if feasible. All transmission of data will occur via encrypted networks and in password-protected files. Any paper-based data sheets utilized for the study will have personal identifiers removed whenever possible and will be stored in the department's locked office. Each subject will be assigned a unique study number for identification, and that number will not be derived from or related to information about the individual. Presentations and publications that result from this study will not contain any individual identifiers other than unique study numbers.

Help

Certificate of Confidentiality

Certificates of Confidentiality constitute an important tool to protect the privacy of research study participants. They are issued by the National Institutes of Health (NIH) to protect identifiable research information from forced disclosure. They allow the investigator and others who have access to research records to refuse to disclose identifying information on research participants in any civil, criminal, administrative, legislative or other proceeding, whether at the federal, state or local level.

Certificates of Confidentiality may be granted for studies collecting information that, if disclosed, could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation. By protecting researchers and institutions from being compelled to disclose information

that would identify research subjects, Certificates of Confidentiality help achieve the research objectives and promote participation in studies by assuring confidentiality and privacy to participants.

ID: 2014-018 Section: PART III - IRB Application - Assessment Procedures
For more information, go to the following website:
http://grants.nih.gov/grants/policy/coc/index.htm
1.0 * Will a Certificate of Confidentiality be obtained for this study?
No
Help
Help
HIPAA
The Healthcare Insurance Portability and Accountability Act (HIPAA) prohibits the use of a person's Protected Health Information without a valid authorization.
1.0 * Will this study record any information which can identify the participants of this study?
Yes
2.0 * Will this study record information that if released, could reasonably place participants at risk of criminal or civil law suits?
No
3.0 * Will this study obtain or review information related to the respondent's medical records or health?
Yes
4.0
Select the option(s) which fits this study:
Name
Self reported medical information
Direct authorization through consent form
Waiver of authorization requested (Full / Partial / Alteration)
HIPAA Waiver
Flow Chart
Help
Waiver of HIPAA Authorization
Pursuant to the Privacy Regulations of HIPAA, an IRB is only permitted to approve a waiver of individual subjects' authorization if it finds and documents specific criteria relevant to the protection of subject privacy.

ID: 2014-018 Section: PART III - IRB Application - Assessment Procedures
1.0 I am seeking:
A full waiver of subject authorization to use and disclose health information during the course of the research study.
· A partial waiver of subject authorization to use and disclose health information only for the purpose of:

Reviewing the operating room schedule to identify potential patients. Coinvestigators other than the treating physician may approach patients to be in the research study.
The following alteration to the authorization requirements:
2.0 * Who will have access to the health information needed for the study? Please identify each person by name or category. Example include: the investigator, the research staff, coinvestigators and their research staffs, and all research monitors.
Principal Investigator: Dr. Enrique Goytizolo
And all IRB approved Co-Investigators
3.0 * Please describe the risks to privacy presented by the research and whether the research presents more than minimal risk of harm to subjects' privacy. Include a description of what identifiers will be reviewed, collected, and stored; who will have access to identified information; how access to study data is controlled; who will monitor access to study data; and where data will be stored:
All patients will be identified by a specific study number. Any patient information taken from medical records will be kept strictly confidential. Only the previously mentioned investigators will have access to this information. Thus our research presents a minimal risk of harm to subjects' privacy.
4.0
* Can the research be practicably carried out without the waiver? Yes No
If it is impracticable to obtain individual authorization, please describe why:
We need to know the patients' demographics to analyze the data collected.
5.0
* Can the research be practicably carried out without access to and use of identified health information? Yes No

ID: 2014-018 Section: PART III - IRB Application - Assessment Procedures
If it is impracticable to conduct this research without access to identified health information, please describe why:
We need to know the patients' demographics to analyze the data collected.
6.0 * What is your plan to protect identifiers from improper use and disclosure?
Any information obtained during the course of this study will be solely for research purposes. Hence only the listed investigators shall have access to this information. Any patient information will be kept locked and secure.
7.0
* Will the patient identifiers be destroyed at the earliest opportunity? Yes No
If yes, describe the plan for destroying identifiers (e.g. how, by whom, and when identifiers will be destroyed):

After data analysis, the study data set will be stored as an Excel or SPSS file. A unique feature of REDCap is that data fields marked as protected health information (PHI) can be automatically de-identified when data is exported. We will utilize this option when closing out the study after data analysis, so that no identifiers remain in the stored Excel or SPSS data set. In the REDCap program, the study will be changed from production mode to archive mode. This means the data and study forms will no longer be accessible to REDCap users. Only the research assistant and research manager will have rights to un-archive the study. The study will be maintained in REDCap for the period of time required by hospital/federal regulations, at which point it will be deleted by the research assistant or research manager.

If no, indicate the health or research justification for retaining the identifiers:

8.0 * Explain how PHI will be acquired and used:

Data will be collected by an investigator or research assistant. Sources of data include medical records and patient physical assessments/interviews conducted by study personnel. Data will be recorded and managed using REDCap electronic data capture tools hosted at the Clinical and Translational Science Center (CTSC) at Weill Cornell Medical College. REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies, providing: 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources. Connection to REDCap occurs via the hospital's encrypted cable and wireless networks, and data will be entered through a password-protected computer terminal or iPad.

9.0

Explain how PHI will be protected during this study:

ID: 2014-018 Section: PART III - IRB Application - Assessment Procedures

Subject privacy and confidentiality will be maintained through the storage of study data in a password-protected computer database maintained by the PI and accessible only to the principal investigator, in addition to other IRB approved study personnel. Each subject will be assigned a unique study number for identification in the study database. This unique study number will not be derived from or related to information about the individual. The key linking this unique study number to patient identifiers (i.e. name, medical record number, date of birth, registry number, etc…) will be maintained in a different password protected database maintained by to which only will have access.

10.0 * Justify your need to collect PHI on this study:

PHI will be needed to screen for potential study participants, verify patient identity, and to coordinate patient information across multiple data sources, including CliniCIS, MMF, PS Reporter, REDCap, and paper charts. Some PHI including age, date of surgery, date of discharge and other unique identifying characteristics are essential data points for creating a demographic profile of

study participants.
Help
Help
PHI Identifiers
1.0
Identify the types of PHI collected:
Name
- Questionnaires or Interviews

Billing Information or Databases
Mental Health Records
Data Registry
- Hospital or Medical Records

Biological Samples
DNA Samples
Other
1.1 If Other, please specify the type of PHI collected:
2.0
Select all the PHI Identifiers that apply:
Identifiers
Names

ID: 2014-018 Section: PART III - IRB Application - Assessment Procedures
Identifiers
Medical Record numbers
All elements of dates (except year) for dates related to an individual:
Help
Data Safety Monitoring Plan
1.0 * Check the one box below that most accurately reflects the plan for data and safety monitoring for this study.
The study will be monitored only by the study investigators and/or sponsor.
1.1 If Other, Please specify your plan for data safety and monitoring for the study. If no DSMB required, Please specify why:
2.0 Describe the clinical criteria for withdrawing an individual subject from the study due to safety or toxicity concerns:
If a patient experiences complications, they will be kept at HSS for observation and withdrawn from the study. Such complications that would cause safety and toxicity concerns include local anesthetic toxicity, cardiac toxicity, and central nervous toxicity.
3.0 Summarize any pre-specified criteria for stopping or changing the study protocol due to safety concerns.
We do not have pre-specified criteria for stopping the study.
4.0 * Are there any plans to perform an interim efficacy analysis:
No
4.1 If you answered Yes, please describe the plans to conduct an interim analysis.
N/A
Help
Final Page

You have completed your application!
Please hit "Continue" to finish the HSS Clinical Trial Form.
Please note that a submission may only be forwarded to the IRB by the Principal Investigator. To do this, the Principal Investigator must press the "SUBMIT STUDY" button in My Activities for this Study ID:2014-018.

ID: 2014-018 Section: PART III - IRB Application - Assessment Procedures
You can track the ongoing status of your submission by logging into the study workspace.
Please feel free to contact the IRB with any questions or concerns.
ID: 2014-018 Section: HSS Clinical Trial Registry
Help

HSS Clinical Trial

The Clinical Trial Registry is posted on the HSS main page to highlight research (including retrospective studies) being conducted at HSS. This same language, once approved by the IRB, can then be used on flyers if you so choose, to post in an effort to recruit subjects.

1.0 Title: The Combination of Adductor Canal Block and Periarticular Injection with an Accelerated Rehabilitation Protocol. A novel technique for Patients Undergoing Total Knee Replacement (ACB PAI)

2.0 PI: Enrique Goytizolo, M.D.

3.0 Co-Investigators:

First Name Middle Name Last Name Title
Jacques YaDeau, MD, PhD IRB Vice Chair
Angie Zhang Research Assistant
Edwin Su, MD
Amar Ranawat, MD
Kara Fields Volunteer
Douglas Padgett, MD
Rupali Joshi Physical Therapist
Isabel Armendi
David Kim, MD
Michael M Alexiades, M.D. MD
Thuyvan Luu
David Mayman, MD
Jodie Curren, RN
Denesy Mancenido Assistant Director, Research
Yi Lin, MD
Matthew Titmuss Physical Therapist
Jennifer Cheng Research Associate
Valeria Buschiazzo
Geoffrey Westrich, MD
Phuong Dinh Mac
Katherine Lee
Iyabo Muse Regional Anesthesia fellow

4.0

Posting date:

ID: 2014-018 Section: HSS Clinical Trial Registry
Name
Upon IRB approval
Post on this date:
5.0
Condition:
Arthroplasty
Other:
6.0 State the summary including number of patients, enrollment period and duration of follow-up (use lay terms):
We plan to enroll up to 114 patients undergoing knee replacement in order to get 96 patients with usable data. All patients will receive peri articular injections as an anesthetic regimen. Half will additionally receive an adductor canal block. Patients will also have an accelerated physical therapy protocol to aid the achievement of rehab milestones. The primary outcome is time when patient is able to meet physical therapy discharge criteria, indicated by the ability to independently negotiate stairs- non-reciprocal (one leg at a time), with or without rails, and with or without assistive device (walker or cane).
7.0 State the inclusion and exclusion criteria (use lay terms):
8.0 State the contact information for the study:
Help