Study Title: Spinal versus General Anesthesia with Popliteal and Adductor Canal Blocks for Ambulatory Foot and Ankle Surgery. A Double-Blinded Randomized Controlled Trial.

NCT#: NCT02996591

IRB#: 2016-0499

Principal Investigator: Jacques T Ya Deau, MD PhD

Study Contact: George Birch

Contact Number: 212-774-7377

Contact Email: birchg@hss.edu

Date: 9/7/2018

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:

Spinal versus General Anesthesia with Popliteal and Adductor Canal Blocks for Ambulatory Foot and Ankle Surgery. A Double-Blinded Randomized Controlled Trial.

* Short Title for EPIC: LMA vs Spinal F&A (If Not Applicable, please enter N/A)

1/18/2017 Print: 2016-0499 - Spinal versus General Anesthesia with Popliteal and Adductor Canal Blocks for Ambulatory Foot and Ankle Surgery. A Double-Blinded...

Date: Wednesday, January 18, 2017 10:33:58 AM

Please click Print here Close ID: 2016-0499 Section: PART I - Study Identification Information

Clinical Research Proposal

https://ecap.hss.edu/eCAP/ResourceAdministration/Project/PrintSmartForms?Project=com.webridge.entity.Entity%5BOID%5B7E7099039664F74FA0FE0FE7... 2/36

to preview Exempt Categories. Expedited Retrospective Chart Review

Click here to Request for

Exemption

preview Study

New Registry

Designs.

Existing Approved Registry

8.0 Select appropriate funding sources for this study:

Name Internally Funded Support

Other Funding Sources:

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

If your study requires CRA review, please upload applicable documents, including sponsor protocol, drug brochure, etc : Name Version LMA vs Spinal F&A Nursing Support Letter 0.01

Help Help 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 * Name Anesthesiology

Help

Date: Wednesday, January 18, 2017 10:33:58 AM

Prin

t Close ID: 2016-0499 Section: PART I - Study Identification Information

H

elp Regulatory Status of Drugs and Devices

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

proposal is: Name Does not apply to this study

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).

Help

Prin

t Close ID: 2016-0499 Section: PART I - Study Identification Information

H

elp 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: 2016-0499 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.

H

elp Specific Aims or Research Questions

1.0 What is the condition or intervention to be studied?

General anesthesia with laryngeal mask airway (LMA) versus spinal anesthesia for foot and ankle surgery, with both groups receiving sciatic nerve blockade in the popliteal fossa plus adductor canal (‘saphenous’) 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.

1) Does general anesthesia with LMA decrease time until PACU discharge compared with spinal anesthesia (when both groups receive popliteal plus adductor canal blocks)?

2) Is there a difference in post-operative pain, nausea, discomfort and needs or opioid consumption with LMA versus spinal anesthesia on top of blocks?

3) Is there a difference in satisfaction from anesthesia with LMA versus spinal anesthesia on top of blocks?

3.0 What is/are the hypothesis(es)?

Our hypothesis is that general anesthesia with LMA with peripheral nerve blocks will be superior in time until PACU discharge (minimum clinically important difference of 45 minutes [Mulroy 2000]) compared to spinal anesthesia with peripheral nerve blocks.

References:

Mulroy MF, Larkin KL, Hodgson PS, Helman JD, Pollock JE, Liu SS. A comparison of spinal, epidural, and general

anesthesia for outpatient knee

ID: 2016-0499 arthroscopy. Section: Anesth PART Analg II 2000;91:860–4.

- Clinical Research Proposal - Nature of Study 4.0 Identify and define the primary outcome and when the outcome will be measured. If measuring change in post- operative function is the most important, that will be your primary outcome.

Time from admission to PACU until ready for discharge home (assessed by RA q 15 m)

Criteria used: Modified Aldrete Scoring System (1) and Marshall and Chung Postanesthesia Discharge Scoring System(2)

References:

1. Aldrete JA. The post anesthesia recovery score revisited. J Clin Anesth 1995; 7:89-91

2. Marshall S, Chung F: Assessment of “home readiness”: Discharge criteria and postdischarge complications. Curr Opin Anaesthesiol 1997; 10:445-50.

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).

NRS pain at rest and with movement (pre-op, PACU, POD1). Patient satisfaction with perioperative care (POD1) Postoperative discomfort and needs (post-op pain, sore throat, back pain, headache, nausea, cold, hunger, thirst) (Pre-op, PACU, POD1) Nausea (Present/absent); if present: 0-10 scale (Preop, PACU, POD1) Headache (Present/absent); if present PDPH questionnaire (Preop, PACU, POD1)

PDPH: post-dural puncture headache Backache (Present/absent); if present, TNS questionnaire (Preop, PACU, POD1)

TNS: transient neurologic symptom Opioid consumption (Preop, PACU, POD1) Side effects (Opioid Related Symptom Distress Scale) (PACU, POD1) Unexpected adverse events, including ICU admission and postoperative complications (Intraop, PACU, POD1) Urinary catheterization (yes/no), time until voiding and volume of intake/output in PACU PQRS Cognitive domain (Preop, PACU, POD 1) Blinding of patient and research assistant (PACU)

Help Help BACKGROUND - Be sure to answer each question individually

1.0 Explain why these research questions are being asked:

Popliteal and adductor canal peripheral nerve blocks (PNBs) provide good pain control for foot and ankle surgery. In the context of the peripheral nerve blocks, spinal anesthesia is typically added to (1) allow surgical use of a thigh tourniquet (2) provide faster onset (and potentially more reliable) surgical anesthesia and (3) ensure patient immobility. However, spinal anesthesia may prolong PACU discharge time and has associated side effects (back pain, headache, TNS – transient neurologic symptoms). General anesthesia also addresses the three concerns discussed previously (tourniquet, reliability, immobility) but when used alone is traditionally associated with higher pain scores, and more nausea. However, the combination of peripheral nerve blocks, general anesthesia (using Laryngeal Mask Airway, LMA), and prophylactic anti-emetics may

ID: 2016-0499 provide good Section: pain control PART with II - fewer Clinical side Research effects from Proposal the general - Nature anesthesia, of Study and hasten the

discharge home as compared to spinal.

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.

Peripheral nerve blocks (PNBs) have increased in popularity due to their efficacy and safety in providing postoperative analgesia by reducing pain, opioid consumption and side effects (1,2). PNBs are often combined with general anesthesia, or neuraxial anesthesia. It is not clear which of these accompaniments most improves the patient experience. When feasible, neuraxial anesthesia is often preferred over general anesthesia because of association with better perioperative outcomes (3). Neuraxial anesthesia may have fewer side effects, such as post-operative nausea and vomiting (PONV)(4) and confusion (5). Spinal anesthesia has advantages over general anesthesia in terms of pain, functional recovery and side effects for ambulatory lower limb surgery, in the absence of peripheral nerve blocks (PNB)(6,7). However, the presumed advantages of neuraxial anesthesia (minimized opioids, improved analgesia and reduced nausea) may possibly also be achieved by combining PNBs with general anesthesia.

The previous non-randomized pilot study applied PNBs plus antiemetic prophylaxis and an opioid sparing protocol among foot and ankle patients (receiving spinal anesthesia plus blocks) and TSA patients (receiving general anesthesia or sedation plus blocks). Results showed low rates of nausea in all groups and no incidence of emesis in any groups. However, no previous studies have compared LMA general anesthesia to spinal anesthesia in the presence of a double block (popliteal + adductor canal) in terms of time to discharge home, satisfaction, severity of pain and PONV, and opioid consumption and side effects in an ambulatory foot and ankle population.

References:

1. Kessler J, Marhofer P, Hopkins PM, Hollmann MV. Peripheral regional anaesthesia and

outcome: lessons learned from the past 10 years. Br J Anaesth 2015; 114: 728-45. 2. Liu SS, Strodtbeck WM, Richman JM, Wu CL. A comparison of regional versus general anesthesia for ambulatory anesthesia: a meta-analysis of randomized controlled trials. Anesth Analg 2005; 101: 1634–42. 3. Memtsoudis SG, Sun X, Chiu, YL, Stunder O, Liu SS, Banerjee S, Mazumdar M,

Sharrock NE. Perioperative comparative effectiveness of anesthetic technique in orthopedic patients. Anesthesiology 2013; 118: 1046-58. 4. Borgeat A, Ekatodramis G, Schenker CA. Postoperative nausea and vomiting in

regional anesthesia: a review. Anesthesiology 2003; 98: 530-47. 5. Kettner, SC. Willschke H, Marhofer P. Does regional anaesthesia really improve

outcome? Br J Anaesth 2011; 107: i90-5. 6. Standl T, Eckert S, Schulteam Esch J. Postoperative complaints after spinal and

thiopentone-isoflurane anaesthesia in patients undergoing orthopaedic surgery. Spinal versus general anaesthesia. Acta Anaesthesiol Scand 1996; 40: 222-6. 7. Liu SS, Strodtbeck WM, Richman JM, Wu CL. A comparison of regional versus general anesthesia for ambulatory anesthesia: a meta-analysis of randomized controlled trials. Anesth Analg 2005; 101: 1634–42. 8. Luu, Roberts, Gadulov, Field, Kahn, Gulotta, Dines, Levine, LaSala, Gordon, Paroli, YaDeau. Recovery Profile among Orthopedic Patients Receiving Peripheral Nerve Blocks: Is General Anesthesia, Spinal Anesthesia or Sedation the Best Accompaniment? A Pilot Study. (Manuscript in preparation)

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

fill.

This study will compare LMA general anesthesia to spinal anesthesia on top of popliteal plus adductor canal blocks for foot and ankle surgery in terms of discharge time, satisfaction and side effects, which has not been done before.

ID: 2016-0499 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?

There is a possibility that in the setting of a double block for foot and ankle surgery, general anesthesia can shorten time to discharge without increasing side effects, compared to spinal anesthesia. This will hopefully lead to more investigative work on general anesthesia with nerve blocks vs spinal anesthesia with nerve blocks that might change the preference of clinicians when deciding upon the best anesthetic regimen for foot and ankle patients.

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 study is comparing two standard of care protocols and will provide information regarding the effectiveness of each. Therefore, this study will not lead to a more definitive protocol or different study.

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

Name Description There are no items to display

Help

ID: 2016-0499 Section: PART II - Clinical Research Proposal - Nature of Study

H

elp 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 – 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:

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:

Standard of care general anesthesia with LMA and spinal anesthesia with popliteal and adductor canal nerve blocks

ID: 2016-0499 Section: PART II - Clinical Research Proposal - Recruitment & Enrollment

H

elp 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:

2.0 Inclusion Criteria: list characteristics that potential subjects and

controls need to have. Use a bullet format, if applicable.

18-75 aged patients

ID: 2016-0499 ASA1-3

Section: PART II - Clinical Research Proposal - Recruitment & Enrollment Elective foot and ankle day surgery procedures, lasting between 1 and 3 hours as per surgeon, performed by 3 co-investigator surgeons. planned for combined popliteal and adductor canal block no contraindications for spinal or LMA general anesthesia

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.

Incapable of providing informed consent, contraindications for regional or LMA anesthesia (anticoagulation, infection at injection site) anticipated difficult airway, BMI>40, anticipated surgical procedure time less than 1 hour or more than 3 hours, Hx of severe PONV ASA >3, peripheral neuropathy affecting the operative extremity pregnant or nursing women, chronic opioid use (daily use of opioids one month prior to surgery/ patients requiring chronic pain interventions) prone position OSA with planned admission overnight to the hospital known allergy/sensitivity to any study medications planned admission after surgery Non-English speaking

4.0 Age Range: 18-75

5.0 Describe how you will identify and recruit potential subjects

for participation in the study.

Surgeon co-investigators will introduce the concept of the study to patients during a preoperative office visit. Potential patients will be identified on the schedule the day before surgery and approached in the holding area of the Hand and Foot Surgery Center, where informed consent will be obtained by a study staff working in conjunction with an attending physician participating in the study. Approximately 2-6 patients per week will be enrolled.

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

Over Course of Study

Help

ID: 2016-0499 Section: PART II - Clinical Research Proposal - Recruitment & Enrollment

H

elp 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.

H

elp Target Enrollment

1.0 * What is the maximum number of subject you plan to enroll in

this study at HSS?(Please enter a number) 36

2.0 If this is a multi-center study, indicate the projected total

subject accrual across all sites.

H

elp ID: 2016-0499 Section: PART II - Clinical Research Proposal - Interventions or Observations

H

elp 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.

Patients will be randomized into either the Spinal/Block Group or General Anesthesia/Block Group. The randomization will be performed by a research staff member not otherwise involved in the project. The patient and research staff performing assessments/administering questionnaires will be blinded to the group assignment.

Intraop-protocol:

Spinal/Block Group: Ultrasound (US) guided sciatic nerve blocks in the popliteal fossa and adductor canal block with 25 mL and 10 mL, respectively, of 0.25% bupivacaine (plus 2 mg preservative-free (PF) dexamethasone / 30 ml), performed under procedural IV sedation protocol. IV sedation protocol: midazolam, 2-5 mg IV + Glycopyrrolate, 0.1 mg IV + Ketamine, 10-20 mg, + propofol as needed. Spinal protocol: 45-60 mg 1.5% mepivacaine, depending on the expected case duration (45 mg for cases with projected duration 1-2 hours, 60 mg

ID: 2016-0499 for cases with Section: projected PART duration II - Clinical 2-3 hours). Research Intraoperative Proposal - sedation Interventions maintained or Observations with propofol infusion and

ketamine, 10 mg/hr (in addition to the 10-20 mg given for block sedation).

General Anesthesia/Block Group. Blocks performed as above. General anesthesia protocol: After induction with propofol and insertion of the LMA, anesthesia maintained with titrated propofol infusion, sevoflurane, ketamine 10 mg/hr (in addition to the 10-20 mg given for block sedation).

Both groups will receive IV ondansetron (4 mg), famotidine (20 mg), dexamethasone (4 mg in addition to block dexamethasone) and ketorolac 30 mg (unless age>75 or weight<60 kg, then 15 mg).

Post-op instructions:

Opioids will not be administered intraoperatively until emergence from sedation (Spinal/Block Group) or from general anesthesia (General Anesthesia/Block group). Tourniquet-related stimuli (being transient in nature) will be addressed with propofol and ketamine (and sevoflurane in general anesthesia group). If patients appear to have surgical pain on emergence, IV hydromorphone will be given as needed (in 0.5 mg increments).

Standardized post-op pain protocol:

Narcotic of choice (Percocet, Norco, Oxycodone, Dilaudid, etc.) with a quantity of 60 pills DVT PPX of choice (aspirin, xarelto, lovenox, etc) Ibuprofen 200mg, take 3 tablets TID for a total of 3 days (quantity 27 pills) Zofran 4mg PO q12h prn nausea for a 2 day supply (quantity 4 pills) No prescribed lyrica or gabapentin to patients enrolled

Collection of outcomes:

Demographics and baseline information (NRS pain, PONV, PQRS Cognitive Domain, backache and headache history, medication consumption, Leiden Discomfort and Needs) will be obtained in the holding area before surgery.

After anesthesia end time, readiness for PACU discharge will be assessed every 15 minutes using the modified Aldrete scoring system. Once the modified Aldrete criteria is met, the patient will be assessed every 15 minutes using the Postanesthesia Discharge Scoring System, which will be used to determine final readiness for PACU discharge time. PACU nurses and physical therapists will assess and instruct the patient with the knowledge of whether the patient received general or spinal anesthesia, but they will be asked not to reveal to the patient which treatment he/she received.

1 hour and 2 hours after PACU admission (or when ready for discharge), NRS pain, PONV, PQRS Cognitive Domain, and Leiden Discomfort and Needs will be assessed. Popliteal and adductor canal blocks will be assessed using an alcohol swab when either spinal wears off or sufficiently awakened from GA. When readiness for PACU discharge is met, ORSDS and blinding assessment will be administered.

On POD 1, patients will be contacted by phone to collect NRS pain, PONV, PQRS Cognitive Domain, Backache/TNS and Headache/PDPH, medication consumption, ORSDS and Leiden questionnaire outcomes, as well as “If you need similar surgery in the future, would you request the same anesthetic that you received this time? (Yes/No)”. If TNS or PDPH is identified, patients will be followed up for duration of symptoms.

Study-Specific Procedures

Day Who?

Before Surgery

Pre-op (Holding Area)

PACU, 1 hour after admission

PACU, 2 hours after admission

PACU, ready for

POD 1 discharge

Identify eligible patients on schedule day before surgery. Confirm length of surgery.

RA X

Obtain consent

Anes MD/ Surgeon

X

Assess readiness for PACU Discharge (q15

RA X (if not met) X (if not met) X (if not met)

ID: 2016-0499 min until criteria Section: met)

PART II - Clinical Research Proposal - Interventions or Observations

NRS pain, PONV, PQRS Cognitive RA Domain

X X

X (if not ready for discharge)

X X

Backache/TNS Headache/PDPH

and

RA X X

Collect opioid and non-opioid consumption

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.

Variable Time point(s) Data Source Who Collects?

Demographics: DOB, MRN, Race, Ethnicity, BMI, Gender, Phone number

RA X

X (for PACU duration)

X

ORSDS RA X X

Leiden Perioperative care Patient Satisfaction questionnaire (LPPSq)

RA X

Leiden Discomfort and Needs

RA X X

X (if not ready for discharge)

X X

Block assessment RA

X

X (when spinal wears off or (Baseline

awakened from reading)

GA)

Blinding Assessment RA X

Pre-op Medical Record Research Assistant

Comorbidities, Risk factors associated with outcomes

Pre-op Medical Record Research Assistant

ID: 2016-0499 Randomization/Group Section: PART assignment II - Clinical Pre-op Research Proposal - Interventions Randomization or Observations scheme

Research Assistant created by staff member not involved in project

ASA, Type of anesthesia, induction time, anesthesia start & end time, difficult spinal/general, TQ time

https://ecap.hss.edu/eCAP/ResourceAdministration/Project/PrintSmartForms?Project=com.webridge.entity.Entity%5BOID%5B7E7099039664F74FA0FE0FE... 13/36

Intra-op Anesthesia Record Research Assistant

Type of surgery, surgery start & end time

Intra-op Medical Record Research Assistant

Time from PACU admission to readiness for PACU discharge

Patient: Aldrete score (Aldrete JA. The post- anesthesia recovery score revisited. J Clin PACU, every 15 minutes

Anesth 1995) and after anesthesia end time

Postanesthesia

Research Assistant

Discharge Scoring System (Marshall and Chung. Curr Opin Anesthesiol 1997)

Opioid consumption Pre-op, PACU, POD 1

Medical Patient

Record and

Research Assistant

Opioid-related side effects PACU (2 hours), POD 1

Patient: ORSDS (YaDeau et al. A&A 2011)

Non-opioid analgesic medications Pre-op, PACU, POD 1

Medical Patient

Record and

Research Assistant

Pain at rest and with movement (at the time of questioning)

Pre-op, PACU (1 hour and 2 hours), POD 1

Patient: NRS (0-10) Research Assistant

Nausea and vomiting

Pre-op, PACU (1 hour Patient: and 2 hours), POD 1

Incidence (yes/no) and severity

Research Assistant (NRS)

Postoperative Quality Recovery Scale (PQRS) Cognitive Domain

Pre-op, PACU (1 hour and 2 hours), POD 1

Patient: PQRS Research Assistant

Satisfaction with perioperative care

Patient: Leiden Perioperative care Patient Satisfaction questionnaire

POD 1

(LPPSq). questionnaire Full

(Caljouw,

Research Assistant

Beuzekom, Boer. BJA 2008). Willingness to get same treatment again

Postoperative discomfort and needs

Patient: Leiden Perioperative care Patient

Pre-op, PACU (1 hour and 2 hours) and POD 1

Satisfaction questionnaire (LPPSq) (Caljouw,

Research Assistant

ID: 2016-0499 Section: PART II - Clinical Research Proposal - Interventions Beuzekom, or Boer. Observations BJA

2008)

Backache/TNS

https://ecap.hss.edu/eCAP/ResourceAdministration/Project/PrintSmartForms?Project=com.webridge.entity.Entity%5BOID%5B7E7099039664F74FA0FE0FE... 14/36

Patient: If the backache question from LPPSq is negative, then no further questioning. If positive, then the TNS Pre-op, POD 1 and POD

questionnaire will be 6-9

administered. Duration

Research Assistant

will be determined from further follow-up as needed. (YaDeau, Liguori, Zayas. A&A 2005)

Headache/ PDPH

Patient: assess for PDPH, including new incidence of postural Pre-op, 6-9

POD 1 and POD

headache (yes/no), severity (NRS), duration.

Research Assistant

On POD6-9 will only ask about headache and backache.

Incidence of urinary catherization, time until voiding and volume of intake/output

PACU

Medical (yes/no)

record: Incidence

Research Assistant

Blinding assessment PACU Patient Research Assistant

Block assessment Pre-op, PACU Patient Research Assistant

Unexpected adverse events, including ICU admission

Intra-op to POD 1 Medical Record Research Assistant

2.0 Who will collect the data:

Jacques YaDeau, MD, PhD IRB Vice Chair Angie Zhang Research Assistant Vincent Lasala, MD Thuyvan Luu Jodie Curren, RN Seong Jin Kim Senior Research Assistant Candace Gopaul Leonardo Paroli, MD Phuong Dinh Mac Kethy JulesElysee, MD Director of Pre-Anesthesia Screening George Birch Richard Kahn, MD

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

for the study). Holding area, PACU, POD 1

4.0

ID: 2016-0499 From what Section: source:

PART II - Clinical Research Proposal - Interventions or Observations Medical Records Patient

No Private Office Charts Please specify which private office:

No Registries Please specify which registry:

Other Please specify:

Help Help General Methods and Procedures

1.0 * Are controls included in the study? No

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.

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):

The surveys and questionnaires that will be administered by the research staff are not standard of care. The Hospital for Special Surgery Anesthesiology Department Research and Education Fund will be used to pay for them.

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 LMA vs Spinal F&A Data Collection Sheet 120116 0.02 LMA vs Spinal F&A Patient Information Sheet 0.01 LMA vs Spinal F&A REDCap 010417 0.04

Help

ID: 2016-0499 Section: PART II - Clinical Research Proposal - Interventions or Observations

H

elp 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

Headache/PDPH Questionnaire

no

Headache/PDPH Questionnaire(0.01)

This instrument will be screen for incidence of puncture headache (PDPH).

used to post-dural

This instrument will be used to View LLPSq yes

LLPSq(0.01)

collect satisfaction with perioperative care.

View

NRS Pain/Nausea/Vomiting

NRS Pain and PONV(0.01)

This instrument will be used to assess for pain, nausea, and emesis.

View

no

This instrument will be used to evaluate 3 symptom distress dimensions (frequency, severity, bothersomeness) for 12 symptoms related to opioid used.

View

ORSDS Questionnaire

yes

ORSDS Questionnaire(0.01)

PQRS Cognitive Domain

PQRS Cognitive Domain(0.01)

This instrument will be used to score cognitive performance.

View

yes

Readiness for This Discharge Questionnaires

instrument will be used to assess if patients are ready to be discharged from the PACU and subsequently, discharged to home.

View TNS Questionnaire yes

Readiness for yes

Discharge Questionnaire(0.01)

TNS Questionnaire(0.01)

This determine neurological instrument if a symptoms patient will be has used (TNS).

transient

to

ID: 2016-0499 Section: PART II - Clinical Research Proposal - Interventions or Observations

H

elp Randomization

1.0 Please state who will do the Randomization:

Research staff who are not affiliated with the study will prepare opaque and sealed randomization treatment envelopes.

2.0 Please state when the Randomization will be done:

The randomization will be done before enrollment begins.

3.0 Please state how the Randomization will be performed:

Randomizer, an Excel-compatible randomizing program, will be used by non-study research personnel to assign treatments, using two treatment arms and a target enrollment of 18 patients per treatment arm. The non-study research personnel will then prepare opaque sealed treatment envelopes.

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

The primary investigator and co-investigators will ensure that randomization is carried out. The research assistants administering surveys/questionnaires and patients will be blinded.

H

elp ID: 2016-0499 Section: PART II - Clinical Research Proposal - Sample Size & Data Analysis

H

elp 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.

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

ID: using 2016-0499 your proposed Section: PART statistical II - Clinical analysis Research plan. Proposal This also - Sample applies Size to & a Data case Analysis 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

1. Proposed analysis (e.g., student's t-test, ANOVA, chi-square,

regression, etc.): Two-sample t-test or Wilcoxon rank-sum test 2. Alpha level: 0.05 3. Beta or power level: 80% 4. Primary outcome variable estimate (mean +/- s.d. for continuous

outcome, frequency/percentage for categorical variable): Mean ± SD PACU length of stay = 132 ± 42 minutes (Luu – unpublished data) 5. Number of groups being compared (use 1 for paired analysis within

the same subjects): 2 6. Effect size or change expected between groups: 45 minutes (Mulroy

2000) 7. Resulting number per group: 16 8. Total sample size required: 32 + additional 10% to account for attrition =

36

References:

Mulroy MF, Larkin KL, Hodgson PS, Helman JD, Pollock JE, Liu SS. A comparison of spinal, epidural, and general anesthesia for outpatient knee arthroscopy. Anesth Analg 2000; 91:860–4.

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:

Balance on demographics and baseline characteristics will be assessed by calculating standardized differences (difference in means or proportions divided by the pooled standard deviation). Balance will be assessed using two thresholds: (1) 1.96 x (2/18)

1/2

= 0.653 and (2) 0.2 (Austin 2009).

The primary outcome will be compared between groups using a two-sample t- test or Wilcoxon rank-sum test. Effect size will be presented as difference in

ID: 2016-0499 means Section: or Wilcoxon-Mann-Whitney PART II - Clinical Research odds with Proposal 95% - confidence Sample Size interval.

& Data Analysis Secondary outcomes with a single measurement per patients will be compared between groups using two-sample t-tests or Wilcoxon rank-sum tests for continuous and ordinal variables, respectively, and χ^2 or Fisher's exact tests, as appropriate, for binary variables. Secondary outcomes measured multiple times per patient will be analyzed using the generalized estimating equations method with an identity link for continuous variables and logit link for binary variables. Effect sizes will be presented as difference in means, Wilcoxon- Mann-Whitney odds, or risk difference and relative risk with 95% confidence intervals. Analyses of secondary outcomes will be considered exploratory.

The success of blinding of the patient and research assistant will be assessed using the Bang Blinding Index (Bang 2010).

All analyses will abide by the intention-to-treat principle.

References:

Austin PC. Balance diagnostics for comparing the distribution of baseline covariates between treatment groups in propensity-score matched samples. Stat Med 2009; 28: 3083-107.

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:

Surgeon co-investigators will introduce the concept of the study to patients during a preoperative visit. Potential patients from the OR schedule will be identified by the research assistant on the day before surgery. Patients' records will be reviewed to determine eligibility. On the day of surgery, the research assistant will approach the patient about the study, and one of the anesthesiologist and/or surgeon co-investigators will review study details and obtain consent.

2.0 Who will obtain informed consent from subjects for this research?

First Name Middle Name Last Name Title Jacques YaDeau, MD, PhD IRB Vice Chair Scott Jacob Ellis, MD Foot and Ankle Surgeon Matthew Roberts, MD Vincent Lasala, MD Thuyvan Luu Leonardo Paroli, MD Kethy JulesElysee, MD Director of Pre-Anesthesia Screening David S. Levine, MD Richard Kahn, MD

H

elp ID: 2016-0499 Section: PART III - IRB Application - Submission Summary

Help IRB Application

1.0 Please provide lay abstract:

The purpose of this study is to determine if there is a difference in patient outcomes with general versus spinal anesthesia when given in addition to popliteal and adductor canal nerve blocks for foot and ankle surgery. Popliteal and adductor canal nerve blocks are injections of local anesthetic agents near nerves in the back and front of the knee going to the foot and ankle that provide numbness during and after surgery. These peripheral nerve blocks offer good pain control and reduce the need for opioids (opioids are pain medications such as morphine, Dilaudid, and oxycodone). General anesthesia involves the flow of oxygen and anesthesia gas through a tube which, along with additional intravenous medications, causes unconsciousness and unawareness of sensations during surgery. Spinal anesthesia involves an injection of local anesthetic in the lower back, which causes numbness below the waist. In addition to spinal anesthesia, a sedative is typically given intravenously to cause relaxation and sleepiness throughout surgery.

General, spinal, and nerve block anesthesia are all routinely used for surgery at the Hospital for Special Surgery. General or spinal anesthesia is typically used in addition to peripheral nerve blocks during foot and ankle surgery to 1) allow the surgeons to use a thigh tourniquet to reduce bleeding, 2) provide anesthesia earlier, and 3) prevent unwanted movement. However, it is unclear whether general or spinal anesthesia provides better patient outcomes when given with peripheral nerve blocks. Some reports show that on its own, spinal anesthesia has advantages over general anesthesia in terms of side effects such as nausea and pain. However, these advantages may also be gained from combining peripheral nerve blocks with general anesthesia. Spinal anesthesia can be associated with headache and backache, although headache and backache can also happen after operations performed with general anesthesia. A previous study at the Hospital for Special Surgery showed low rates of nausea among patients who received nerve blocks with spinal anesthesia, and no nausea among patients who received a nerve block with general anesthesia. Therefore, the primary aim of this study is to determine if, as a treatment, either general or spinal anesthesia has advantages over the other treatment in terms of side effects, pain, patient satisfaction, and time it takes to leave the hospital in an ambulatory foot and ankle population.

2.0 * Requested Review Type:

Full IRB Review

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

4.0 * Is Genetic Testing involved in this study? No

H

elp Assessment of Research Procedures

1.0 Describe any potential for direct benefits to participants in this

study:

Due to the nature of this study, which is comparing two standard of care treatments, patients may not receive any direct benefit from participating. However, patients who receive general anesthesia with peripheral nerve blocks might meet discharge criteria earlier after surgery because their discharge will not be delayed by the time it takes for spinal anesthesia to resolve. Therefore, patients who receive general anesthesia may be released to the comfort of their own home earlier than patients who receive spinal anesthesia.

2.0 Describe any potential benefits to society:

This study would increase our understanding of whether general or spinal anesthesia provides better patient outcomes when given with peripheral nerve blocks. Previous studies that have compared general and spinal anesthesia without peripheral nerve blocks have shown that spinal anesthesia leads to lower rates of nausea and opioid use. However, these advantages may also be gained from combining peripheral nerve blocks with general anesthesia, so this study will help determine how general anesthesia compares to spinal anesthesia in terms of patient outcomes when used in conjunction with peripheral nerve blocks.

H

elp Greater Than Minimal Risk - Radiographs/CT/MRI Test

1.0 Describe potential non-radiographic risks of the research study and assess their likelihood and seriousness.

The popliteal and adductor canal nerve blocks are very commonly performed at HSS for foot and ankle surgery under ultrasound guidance. There is a chance that the nerve may become irritated or injured during the injection; however, the risk is very small. Ultrasound is safe and involves no ionizing radiation.

General anesthesia and spinal anesthesia are both commonly used at HSS, as well as other hospitals, and are considered safe and effective. It is not clear whether spinal or general anesthesia is safer for patients such as yourself. There are potential rare serious complications from both types of anesthesia. Potential rare risks of general anesthesia include problems with the heart, lungs, and cognition (thinking) after surgery. These complications may be more likely with older patients. Potential rare risks of spinal anesthesia include spinal cord injury. Older patients are more likely to have conditions that increase the risk of spinal cord injury. Most patients having spinal anesthesia for foot and ankle surgery receive intravenous sedation, so that they are ‘asleep’ during surgery. Sedation has potential rare serious complications such as problems with the lungs and cognition (thinking) after surgery.

There are less serious potential risks from general anesthesia and spinal anesthesia. It is possible that patients receiving general anesthesia will be more likely to have a sore throat from the tube used to keep the airway open (a laryngeal mask airway will be used if possible). Some studies suggest that nausea and vomiting are more likely with general anesthesia (but a recent study at HSS showed no nausea after general anesthesia). It is possible to have a headache or backache after spinal anesthesia, but most headaches and backaches after surgery are not from the anesthetic. If you experience prolonged numbness from the spinal, this may cause a longer stay in the hospital, but this possible delay is in terms of hours. We will attempt to avoid prolonged numbness from the spinal by choosing an appropriate amount of local anesthetic.

Participation in this research involves the potential risk of a breach of confidentiality to your stored health information. HSS tries to minimize those risks by (i) removing some direct identifiers from stored information (i.e., names, social security numbers, medical record numbers); (ii) securing, in a separate location, and limiting access to information that would identify you; and (iii) limiting access to information stored to HSS investigators.

2.0

If radiographs/CT/MRI are included in the research study, please selected the applicable tests with standard wording for risks from the list below:

Please contact Roseann Zeldin (212-

Name Risk Description

Ultrasound is an extremely safe procedure with no known untoward Ultrasound

effect using diagnostic frequencies. Ultrasound involves no ionizing radiation.

606-1025) for specific exposure values for all radiographs sought.

Help

H

elp Greater Than Minimal Risk

1.0

Describe measures that will be used to minimize physical risks. Where appropriate, discuss provisions for insuring medical and professional intervention in the event of adverse effects to the subject. For example, what precautions are in place to prevent and/or treat potential physical risks which may arise from research related procedures (i.e. infections, DVTs, etc...).

All medical procedures involved in the study are standard of care. All patients will undergo routine monitoring before, during, and after surgery, and information regarding any post-discharge complications will be provided by the clinical team.

Please contact Roseann Zeldin (212- 606-1025) for specific exposure values for all radiographs sought.

2.0 Discuss why the risks to the subjects are reasonable in

relation to the anticipated benefits and the importance of knowledge that may be expected to result. State to which patients your study results should apply. If you get a result, what will be its significance to physicians and their patients?

Both general and spinal anesthesia are standard of care treatments and patients would receive one of these treatments regardless of whether they participate in the study or not. The benefit of understanding whether general or spinal anesthesia provides better patient outcomes when given with peripheral nerve blocks will be important to physicians and their patients. Physicians will be able to recommend the more advantageous treatment for their patients and perhaps the stigma behind general anesthesia will be reduced.

3.0 Describe any alternative treatments and procedures that

might be advantageous to the subjects:

Patients will receive either general or spinal anesthesia with peripheral nerve blocks, regardless of whether they participate in the study or not, but they will not know which treatment they receive if they choose to participate. The alternative is choosing whether to receive general or spinal anesthesia with peripheral nerve blocks.

H

elp 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 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:

While some surveys we are using are validated in English, not all of the surveys are. Therefore, we cannot include non-English speaking participants.

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

H

elp 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.

Lay term Glossary 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.

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

Patient Information- LMA vs Spinal 12_1_16.docx

12/1/2016 PM

H

elp Data Privacy & Confidentiality

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

Data will be collected via patient interviews (in person at hospital and over the phone postoperatively) and medical records. All data will be recorded in password- protected REDCap and medication usage (Excel) databases. Study files will be maintained in an encrypted folder on a shared drive.

2.0 Select Data Recording Identifiers used on this study:

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

https://ecap.hss.edu/eCAP/ResourceAdministration/Project/PrintSmartForms?Project=com.webridge.entity.Entity%5BOID%5B7E7099039664F74FA0FE0FE... 25/36

2:21

0.01

C1 Ya Deau 2016-0499 Informed consent (revised 12-01- 16).docx

12/1/2016 PM

2:14

0.03

YaDeau LMA vs Spinal FA Informed Consent Form

11/4/2016 AM

9:21

0.02

Assent Form For Adolescent Participation In Research Study

Informed Consent To Participate In A Genetic Research Study

Informed Consent To Participate In Research

2.1 If Other is selected, please specify:

Data will be stored in a password-protected REDCap database. Data will be entered by research personnel on a password-protected computer or tablet. Subject privacy and confidentiality will be maintained through the storage of study data in a password-protected computer database maintained by the research staff and accessible only to the principal investigator (Dr. YaDeau), 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.

3.0 Where will the research data be stored? Please specify the

physical location and how it will be secured to protect confidentiality:

Research administrators and auditors within our research group will have access to the study records and data. This is required for regulatory maintenance. These individuals include Denesy Mancenido (Clinical Research Manager, HSS) and Jodie Curren (Auditor; Clinical Research Supervisor, HSS). At the time of data analysis, the biostatistician (Kara Fields, HSS) will have access to the limited dataset.

4.0 Who, other than the specified study team, will have access to

the study records or data? Specify their name, role, and affiliation.

Data will be released to the project's statistician at the end of the 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.

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:

The study will undergo data analysis by a statistician upon completion, and the 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 can be automatically de- identified when data is exported. We will utilize this option when closing out the study after data analysis, so that limited 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.

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:

Audio/video recordings and photographs will not be used.

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:

Audio/video recordings and photographs will not be used.

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 entered into REDCap, which is a password-protected database hosted at HSS. Study personnel will enter the data, and routine audits will be performed to ensure quality.

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.

Subject privacy and confidentiality will be maintained through the storage of study data in a password-protected computer database maintained by Dr. YaDeau and accessible only to the principal investigator (Dr. YaDeau), 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) will be maintained in a different password-protected database maintained by Dr. YaDeau, to which only Dr. YaDeau and Dr. YaDeau will have access. Immediately following data entry into the password-protected databases, the paper-based data collection instruments will be stripped of all personal identifiers and stored in a locked file cabinet maintained by Dr. YaDeau. The page containing patient identifiers will be stored separately in a locked file cabinet in the Anesthesiology Research Office, and will be destroyed at the earliest opportunity upon completion of the study. Presentations and publications that result from this study will NOT contain any individual identifiers other than unique study numbers.

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

H

elp 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.

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

H

elp 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)

https://ecap.hss.edu/eCAP/ResourceAdministration/Project/PrintSmartForms?Project=com.webridge.entity.Entity%5BOID%5B7E7099039664F74FA0FE0FE... 28/36

HIPAA Waiver Flow Chart

H

elp 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.

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:

screening potential patients for study eligibility. We will need to review potential patients' medical records to determine whether they are eligible for the 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, co-investigators and their research staffs, and all research monitors.

All members of the study team will have access to the health information for the study. In addition, the auditors in our research group will have access. Research administrators will also have access.

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:

Subject data will be maintained in a password-protected database (REDCap). Aside from auditors, non-study personnel will not have access to the data. In addition, the database will be assessed using a password-protected computer or iPad. Medication data will be kept in a password-protected folder. Measures will be taken to maintain subject privacy. Each subject will be assigned a unique study number of identification in the database. For screening purposes, preop medical records and history will be reviewed for each subject. No information will be collected until the subject is deemed eligible, and written informed consent is obtained. The following patient identifiers will be collected: name, MRN ID, date of surgery, and telephone numbers. Other data will be collected via medical chart review (medications) and patient interactions (in person or phone calls). Upon study completion, a statistician will receive a data set with all possible identifiers removed, and these study files will be de-identified and archived once accepted for publication.

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:

A partial waiver is needed, as non-treating providers will be accessing health information (e.g., research assistant, research associate) for screening and follow- up purposes.

5.0

* Can the research be practicably carried out without access to and use of identified health information? Yes No

If it is impracticable to conduct this research without access to identified health information, please describe why:

Names and telephone numbers are needed for postoperative follow-ups. MRN IDs are needed to look up patients' medical records. Therefore, access to identified health information is essential.

6.0 * What is your plan to protect identifiers from improper use

and disclosure?

No identifiers will be included in any presentations or publications that result from this study. Only the listed investigators will 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):

Each subject will be assigned a unique study number that will not be derived from or related to identifiers. Immediately following data entry into the password- protected databases, any paper-based data collection instruments will be stripped of all personal identifiers by the research assistant and stored in a locked file cabinet maintained by the principal investigator. The page containing patient identifiers will be stored separately in a locked file cabinet in the Anesthesiology Research Department, and it will be destroyed at the earliest opportunity upon completion of the study.

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

8.0 * Explain how PHI will be acquired and used:

PHI will be acquired by the research assistants or investigators throughout the hospital stay. Demographic and medication information will b obtained from medical records. Study outcome-related data will be collected via patient interactions, either in person (day of surgery) or by phone (postoperative day 1). Data will be recorded and managed using REDCap electronic data capture tools hosted at the Clinical and Translational Science Center at Weill Cornell Medical College. Connection to REDCap occurs via the hospital's encrypted cable and wireless networks, and data will be entered through a password-protected computer or iPad. Medication usage will be recorded in Excel, and the file will be kept in a password-protected folder on a private drive.

9.0

Explain how PHI will be protected during this study:

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.

Subject privacy and confidentiality will be maintained through the storage of study data in a password-protected REDCap database maintained by the PI, Dr. Jacques YaDeau, and accessible only to the principal investigator and 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 and is autogenerated on REDCap. Data, including paper-based data collection instruments that are stripped of all personal identifiers, will also be stored in folders located in a locked cabinet in the Anesthesiology Research Office.

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

PHI will be need to look up preop and periop information in medical charts. It will also be needed for postop phone follow-ups.

Help

H

elp 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 Telephone Numbers Medical Record numbers Any other unique identifying numbers, characteristics, or code

H

elp 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:

Subjects will be kept overnight at HSS for monitoring and treatment if they develop complications and do not meet the criteria for discharge on the day of surgery.

3.0 Summarize any pre-specified criteria for stopping or changing

the study protocol due to safety concerns.

General and spinal anesthesia have both been proven to be safe and effective, but if new information arises that either is considered unsafe at any point, immediate changes will be made to the protocol and informed consent form.

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.

H

elp 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:2016-0499.

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: 2016-0499 Section: HSS Clinical Trial Registry

H

elp HSS Clinical Trial

The ID: 2016-0499 Clinical Trial Registry Section: is posted HSS on Clinical the Trial HSS Registry 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: Spinal versus General Anesthesia with Popliteal and Adductor Canal Blocks

for Ambulatory Foot and Ankle Surgery. A Double-Blinded Randomized Controlled Trial.

2.0 PI: Jacques YaDeau, MD, PhD

3.0 Co-Investigators:

First Name Middle Name Last Name Title Angie Zhang Research Assistant Scott Jacob Ellis, MD Foot and Ankle Surgeon Matthew Roberts, MD Kara Fields Volunteer Vincent Lasala, MD Jodie Curren, RN Seong Jin Kim Senior Research Assistant Leonardo Paroli, MD Phuong Dinh Mac Kethy JulesElysee, MD Director of Pre-Anesthesia Screening George Birch David S. Levine, MD Richard Kahn, MD

4.0

Posting date: Name Upon IRB approval

Post on this date:

5.0

Condition: Foot and Ankle Conditions

Other:

6.0 State the summary including number of patients, enrollment

period and duration of follow-up (use lay terms):

This study is looking at ambulatory foot and ankle surgery patients to determine if they experience a difference in their recovery after receiving popliteal and adductor canal nerve blocks with either general anesthesia or spinal anesthesia. Popliteal and adductor canal nerve blocks are injections of local anesthetic agents near nerves in the back and front of the knee going to the foot and ankle that provide numbness during and after surgery. These peripheral nerve blocks offer good pain control and reduce the need for opioids (opioids are pain medications such as morphine, Dilaudid, and oxycodone). General anesthesia involves the flow of oxygen and anesthesia gas through a tube which, along with additional intravenous medications, causes unconsciousness and unawareness of sensations during

ID: 2016-0499 surgery. Spinal anesthesia Section: involves HSS an Clinical injection Trial of Registry local anesthetic in the lower

back, which causes numbness below the waist. In addition to spinal anesthesia, a sedative is typically given intravenously to cause relaxation and sleepiness throughout surgery.

General, spinal, and nerve block anesthesia are all routinely used for surgery at the Hospital for Special Surgery. General or spinal anesthesia is typically used in addition to peripheral nerve blocks during foot and ankle surgery to 1) allow the surgeons to use a thigh tourniquet to reduce bleeding, 2) provide anesthesia earlier, and 3) prevent unwanted movement. However, it is unclear whether general or spinal anesthesia provides better patient outcomes when given with peripheral nerve blocks. Some reports show that on its own, spinal anesthesia has advantages over general anesthesia in terms of side effects such as nausea and pain. However, these advantages may also be gained from combining peripheral nerve blocks with general anesthesia. Spinal anesthesia can be associated with headache and backache, although headache and backache can also happen after operations performed with general anesthesia. A previous study at the Hospital for Special Surgery showed low rates of nausea among patients who received nerve blocks with spinal anesthesia, and no nausea among patients who received a nerve block with general anesthesia. Therefore, the primary aim of this study is to determine if, as a treatment, either general or spinal anesthesia has advantages over the other treatment in terms of side effects, pain, patient satisfaction, and time it takes to leave the hospital in an ambulatory foot and ankle population. To do this, 36 patients will be randomly assigned to receive, along with popliteal and adductor canal blocks, either general anesthesia or spinal anesthesia. In the recovery room after surgery, patients will be assessed every 15 minutes for readiness for discharge. Other postoperative assessments (pain, nausea, cognitive ability, backache, headache, sore throat, discomfort, opioid-related side effects and satisfaction) will be made in the recovery room and via phone on POD 1.

7.0 State the inclusion and exclusion criteria (use lay terms):

Inclusion criteria

18-75 aged patients ASA1-3 Elective foot and ankle day surgery procedures, lasting between 1 and 3 hours as per surgeon, performed by 3 co-investigator surgeons Capable of providing informed consent in English Planned for combined popliteal and adductor canal block No contraindications for spinal or LMA general anesthesia

Exclusion criteria

Incapable of providing informed consent, Contraindications for regional or LMA anesthesia (anticoagulation, infection at injection site) Cnticipated difficult airway, BMI>40, Anticipated surgical procedure time less than 1 hour or more than 3 hours, Hx of severe PONV ASA >3, Peripheral neuropathy affecting the operative extremity Pregnant or nursing women, Chronic opioid use (daily use of opioids one month prior to surgery/ patients requiring chronic pain interventions) Prone position OSA with planned admission overnight to the hospital Known allergy/sensitivity to any study medications Planned admission after surgery

ID: 8.0 2016-0499 State the contact information Section: HSS Clinical for the Trial study:

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Help