Success of External Cephalic Version With Immediate Spinal Anesthesia Versus Spinal Anesthesia When Attempt
Without Anesthesia Has Failed: A Randomized Controlled Trial.

PI: Natalie Porat
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Mount Sinai

Icahn School of Medicine at Mount Sinai
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Mount Sinai St. Luke's
Mount Sinai West

Program for the Protection of Human Subjects
Institutional Review Boards

Mount Sinai Health System
One Gustave L. Levy Place, Box 1081
New York, NY 10029-6574
T 212-824-8200
F 212-876-6789
irb@mssm.edu
icahn.mssm.edu/pphs

Initial Application
IRB-17-01230
Natalie Porat

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1. Summary - Title

Protocol Title

Success of External Cephalic Version With Immediate Spinal Anesthesia Versus Spinal Anesthesia When Attempt Without Anesthesia Has Failed: A Randomized Controlled Trial.

Principal Investigator	Natalie Porat
Primary Department	Obstetrics/Gynecology
Application Initiated By	Natalie Porat

Lay Summary

This is a randomized controlled trial assessing the success of external cephalic version (ECV). When patients are noted to be in breech presentation (bottom of baby facing down) at 37 weeks gestation they are encouraged to undergo an ECV procedure (an external rotation done by the obstetrician) which rotates the baby to a cephalic presentation (head facing down) in order to allow for vaginal delivery. Patients who fail this procedure undergo a cesarean section if the baby has still not rotated by the time of delivery. At our institution, this is usually done by giving a tocolytic (relaxant to the uterus) and performing the procedure. In rare cases the patient may be offered spinal anesthesia, particularly when the attempt was unsuccessful without anesthesia and the provider believes that anesthesia will facilitate success or if the patient is not tolerating the procedure due to pain. Randomized control studies and a recent meta-analysis have suggested that spinal anesthesia increases the success rate of ECV significantly and decreases the number of cesarean sections. However, there have been limited studies on using spinal anesthesia only if the procedure fails without it. Our study aims to randomize patients who present for ECV into two groups. Group 1: patients who receive spinal anesthesia immediately and Group 2: patients who receive spinal anesthesia only if the procedure first fails without it. Comparing these two groups is essential in order to optimize ECV procedure protocols with the highest success and least invasive approach.

IF Number IF1989320

2. Summary - Setup

Funding Has Been Requested / Obtained	No
Application Type	Request to Rely on Mount Sinai IRB
Research Involves	Prospective Study ONLY
Consenting Participants	Yes
Requesting Waiver or Alteration of Informed Consent for Any Procedures	No
Humanitarian Use Device (HUD) Used Exclusively in the Course of Medical Practice	No
Use of an Investigational Device to Evaluate Its Safety or Effectiveness	No
Banking Specimens for Future Research	No
Cancer Research that Requires Approval from the Protocol Review and Monitoring Committee (PRMC)	No
Clinical Trial	Yes

**** A prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices).***
**** Used to determine whether new biomedical or behavioral interventions are safe, efficacious, and effective.***

Drugs / Biologics	No

**** Drugs / Biologics That Are Not a Part of Standard Practice * Controlled Substances * Drugs / Biologics Supplied by the Research Sponsor or Purchased with Study Funds***

Radiological Procedures	No
Hazardous Materials	No

**** Recombinant DNA * Viral Vectors * Plasmids * Bacterial Artificial Chromosomes * Toxic Chemicals, Potentially Toxic Medications, Carcinogens * Autologous Cell Lines***

Request Use of Clinical Research Unit Resources	No

3. Summary - Background

Objectives

To test the hypothesis that patients undergoing ECV with spinal anesthesia will have the same rate of success as those undergoing the procedure without anesthesia initially with reattempting using spinal if unsuccessful.

Background

Breech presentation occurs in approximately 3-4% of term pregnancies and leads to one of the most common indications for cesarean delivery. Attempting an external cephalic version (ECV) significantly increases the chance of cephalic presentation at time of delivery and reduces the chance of cesarean section(1). Since ECV does in fact reduce the rate of cesarean section, many studies have sought to determine the best method to perform the procedure to optimize the chance of success. A recent meta-analysis concluded that administration of neuraxial analgesia significantly increases the success rate of ECV and also increases the incidence of vaginal delivery(2). However, there have been only 2 prospective studies and no randomized trials that evaluated the success of ECV using neuraxial analgesia only when initial attempt without it has failed(3,4). Therefore, we would like to design a randomized controlled trial with two groups: Group 1- patients receiving spinal anesthesia immediately versus Group 2- patients attempting ECV without spinal anesthesia with reattempt using a spinal if first attempt fails. This study would be conducted on labor and delivery at Mount Sinai West hospital. Patients who present to labor and delivery at term for ECV would be approached for enrollment and those who consent to be part of the study would be randomized into a group. ECV would then be attempted and delivery and neonatal outcomes would be collected. Patients would likely be enrolled in the study from time of version (appox 37 weeks) until postpartum. This study will take approximately 1-2 years given our ECV rate. References: 1. Hofmeyr GJ, Kulier R, West HM. External cephalic version for breech presentation at term. Cochrane Database of Syst Rev2015;4: CD000083. 2. Magro-Malosso ER, Saccone G, Di Tommaso M, Mele M, Berghella V. Neuraxial analgesia to increase the success rate of external cephalic version: a systematic review and metaanalysis of randomized controlled trials. Am J Obstet Gynecol 2016;215:276-86. 3. Neiger R, Hennessy MD, Patel M. Reattempting external cephalic version under epidural anesthesia. Am J Obstet Gynecol 1998;179:1136-9. 4. Rozenberg P, Goffinet F, de Spirlet M, Durand-Zaleski I, Blanie P, Fisher C, Lang AC, Nisand I: External cephalic version with epidural anaesthesia after failure of a first trial with beta-mimetics. BJOG 2000; 107:406-10.

Primary and Secondary Study Endpoints

The primary outcome will be the success rate of external cephalic version to cephalic presentation. Secondary outcomes will include: time from procedure to delivery, mode of delivery, patient discomfort, adverse events during procedure (ie.fetal bradycardia, emergent cesarean section, abruption), neonatal outcomes (ie. birthweight, Apgars, cord pH, NICU admission). The external cephalic version procedure may be terminated in any patient at any time regardless of this study in the event of persistent fetal heart rate abnormalities, maternal request, or any other adverse findings that the physician believes is an indication that the procedure must be terminated.

Protocol Was Already Approved by the Icahn School of Medicine at Mount Sinai (ISMMS) Institutional Review Board (IRB) Under a Different Principal Investigator	No

Protocol Was Previously Submitted to an External(non-ISMMS) IRB	No

4. Research Personnel

Name/Department	Role/Status	Contact	Access	Signature Authority	Phone	Email
Natalie Porat / Obstetrics/ Gynecology	PI /	Yes	SIGNAUTH			
Lois Brustman / Obstetrics/ Gynecology	Co-Investigator /		EDIT			
Barak Rosenn / Obstetrics/ Gynecology	Co-Investigator /		EDIT			
Zainab Al-Ibraheemi / Obstetrics/ Gynecology	Co-Investigator /		EDIT			
Dyese Taylor / Obstetrics/ Gynecology	Co-Investigator /		EDIT			
Migdalia Saloum / Anesthesiology	Co-Investigator /		EDIT			
Julio Marenco / Anesthesiology	Co-Investigator /		EDIT			
Jason White / Anesthesiology	Co-Investigator /		EDIT			

5. Sites

Site Name	Mount Sinai West
Other External Site Name	
Contact Details	
Approved	0
Approval Document	
Funded By Mount Sinai	1
Reviewed By	Mount Sinai IRB
Other IRB	

6. Subjects - Enrollment

Site Name	Mount Sinai Roosevelt
Subjects To Be Enrolled	
100	
Total	100

7. Subjects - Setting and Resources

Setting of Human Research Other

Specify Other Setting of Human Research

Labor and Delivery unit at Mount Sinai West hospital.

Total Number of Subjects Needed To Complete Study 100

Feasibility of Meeting Recruitment Goals

From 2012-present we have attempted approximately 89-115 external cephalic versions a year. Each year we have been increasing in numbers, with 115 patients in 2015. These numbers only include patients who had an attempted ECV and does not include patients that were scheduled for ECV but the procedure was not performed for various circumstances. Given this information we believe that it will take approximately 1-2 years to recruit 100 patients.

Facilities To Be Used for Conducting Research

We will be conducting our research on labor and delivery and the MFM fellow office located in Mount Sinai West Hospital, suite 10-C.

Multi-Center Study No

Community-Based Participant Research Study No

PI must attest to the following. * Process is adequately described to ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product(s), and their trial-related duties and functions.

8. Subjects - Populations

Inclusion Criteria

Singleton pregnancies of at least 37 weeks gestation in nonvertex presentation with no contraindication for a vaginal delivery. Membranes must be intact with a minimum of a 2x2 pocket and Category 1 non-stress test.

Exclusion Criteria

All patients with a contraindication for a vaginal delivery will be excluded from the study, as well as those patients with gross fetal anomalies or uterine malformations. Patients with contraindications to neuraxial anesthesia or allergies to any of the study medications will also be excluded.

Enrollment Restrictions Based Upon Gender, Pregnancy, Childbearing Potential, or Race	Yes

Justify Restriction(s)

Patient must be pregnant in order to enroll because this is a study involving fetal versions.

Age Range(s)	18 to 64 Years
Targeted Population(s)	Adults - Patients , Pregnant Women

Other Aspects that Could Increase Subjects Vulnerability

There are no further aspects that could increase the subjects vulnerability.

Safeguards to protect Subjects rights and welfare

In order to protect the subjects rights we will be consenting the patients and allowing them to decide if they would like to participate. Patients will be assured that their decision to participate in the study is completely optional and that their care will not be altered in the event that they do not wish to participate. Patients will be given time to decide if they would like to participate and all questions will be answered.

9. Subjects - Participation

Duration of an Individual Subjects Participation in the Study

The individual subject will be participating in the study for approximately 1-8 hours depending on how long the procedure takes. We will then follow-up their delivery information using labor and deliveries' EMR (Peribirth). The patient will not be contacted at this time. Once delivered they will no longer be part of the study. Delivery usually occurs within 5 weeks of the procedure given that the procedure is only done at 37 weeks or higher.

Duration Anticipated to Enroll All Study Subjects

We will be enrolling study subjects for 2 years.

Estimated Date for the Investigators to Complete This Study Within two years

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Procedures for Subjects to Request Withdrawal

Patients can withdraw at anytime and will be aware of that option. We will be conducting an intention-to-treat analysis. If the patient decides to withdraw we will then ask the patient if we can still collect their demographic and delivery data. If they allow this, then they will be included in the analysis and this will be stated in our results once the study is written. No identifiers will be included in the results. If they would like to withdraw completely we will not collect any further data and we will not include them in our analysis.

Procedures for Investigator to Withdraw Subjects

There is no circumstance that the patient will be withdrawn without their consent. There is no anticipated reason that a patient would need to be terminated from the study. If there is any concern that there is risk to the fetus during the procedure, the procedure will be terminated and the patient will still be included in the study. This will then be discussed and explained in our study results.

Participants Will Be Recruited Yes

Recruitment Method(s) Clinical Practice

How Participants Will Be Identified

Each day external cephalic versions are scheduled on labor and delivery. When a patient is noted to be scheduled for a version, once they are admitted and there is no contraindication noted for the participation in the study (for example, they come for a version but are found to be in the cephalic presentation that day) they will be asked if they are willing to participate in a study. If the patient agrees, a member of the research team will approach the patient and discuss the study with the patient.

Who Will Initially Approach Potential Participants Study Personnel

How Research Will Be Introduced to Participants

Once they are admitted for a version and there are no contraindications for the procedure, the patient will be asked if they are willing to participate in a study. If so, a member of the research team will approach the patient. In a private setting, they will be introduced to the study and will be given as long as they need to decide whether they would like to participate in the study. Since the patient will be receiving IV hydration prior to the procedure (whether or not they are going to be part of the study), they will be given as long as it takes for the IV fluids to run. This is usually between 30 minutes to an hour. If they need more time to decide, they will be given additional time as needed.

How Participants Will Be Screened

Participants will be screened by looking at the scheduling book each day.

10. Subjects - Risk and Benefits

Risks to Subjects

Overall, there is a minimal risk to subjects who participate in this study. In terms of the procedure itself, there have been adverse events reported after ECV including placental abruption, umbilical cord prolapse, rupture of membranes, stillbirth and fetomaternal hemorrhage. These adverse events are rare, occurring in less then 1% and thus the American College of Obstetrics and Gynecology (ACOG) does endorse attempting ECV when possible in centers where prompt evaluation and, if necessary, cesarean delivery is readily available. In regards to neuraxial analgesia, Magro-Malosso et. al, recently performed a metal analysis comparing use of neuraxial analgesia versus controls during ECV attempts and found no difference in adverse outcomes between groups (emergency cesarean delivery, transient bradycardia, nonreassuring fetal testing, or placental abruption). It does appear that patients who do not receive neuraxial analgesia do experience more discomfort during the procedure.

Description of Procedures Taken to Lessen the Probability or Magnitude of Risks

In order to lessen the magnitude of risks, patients will be monitored for at least 30 minutes post procedure as recommended by ACOG, or longer if fetal testing is non-reassuring. In addition, procedure attempts will be terminated if the provider believes there is risk to the fetus at any time. This procedure is also done under ultrasound guidance to monitor the fetus throughout. Lastly, patients will be given strict post procedure precautions for when they are discharged from the hospital.

Provisions for Research Related Harm / Injury

There is no anticipated research related harm for study subjects. There is a very small risk of adverse outcomes inherent in the procedures themselves, but this is not due to participating in research. Medical personal will be readily available for any adverse outcome as is standard for all pregnant patients in such events.

Expected Direct Benefit to Subjects

Each subject may be expected to directly benefit from participation in this study. For those that are in the immediate spinal group, these patients may benefit from less discomfort (as is noted in prior studies) and an increased external cephalic version success rate (compared to controls). Those who are in the spinal anesthesia only if ECV fails without it, may benefit from not having to undergo an additional procedure (neuraxial anesthesia) when attempt leads to cephalic presentation with ease. It is unclear if these patients will have the same ECV success rate, but prior non-randomized trials do suggest this finding.

Benefit to Society

The results of this study may benefit society in that a better protocol may be in place for ECV attempts that increases the rates of success without increasing the rate of risk or cost.

Provisions to Protect the Privacy Interests of Subjects

The patients will be approached by the a member of the study team on the labor floor to determine if they are willing to be included in the study. Their participation will not require any additional examinations. They will only be approached once by the study team on the labor floor to determine if they are willing to participate. All research-related discussions will be held in the patient's private room. Any questions will be answered and fully discussed to maximize patient comfort. Patients will be allowed time to consider participation and we will explain to patients that we will follow up their delivery information, but will not contact them directly. We will also assure the patient all the steps that will be taken to protect their privacy.

Economic Impact on Subjects

We do not see any foreseeable additional costs to subjects for participating in this research study. The patient is already in the hospital to undergo a version and anesthesia may or may not be used for this procedure even when not participating in the study.

11. Subjects - Pregnant Women

Preclinical Studies Including Those on Pregnant Animals and Clinical Studies Including Those on Non-Pregnant Women Have Been Conducted No

Data for Assessing Potential Risks to Pregnant Women and Fetuses

There have been many studies on pregnant women undergoing external cephalic versions. These studies have concluded that attempting ECV is beneficial, and use of neuraxial anesthesia also increases success rates and decreases cesarean section rates. They have also found no increased rate of adverse outcomes. Since this procedure is only performed in the third trimester no inducements, monetary or otherwise, will be offered to terminate a pregnancy. Individuals engaged in the research team will have no part in any decisions as to timing, method, or procedures used to terminate a pregnancy. Individuals engaged in the research will have no part in determining the viability of a neonate.

PI must attest that all of the following are true. * No inducements, monetary or otherwise, will be offered to terminate a pregnancy. * Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy. * Individuals engaged in the research will have no part in determining the viability of a neonate.

12. Procedures - Narrative

Description of the Study Design

This is a randomized controlled trial comparing two groups. Patients will be admitted to labor and delivery for external cephalic version. They will be approached by a member of the research team if they are eligible to participate. If they choose to consent, they will be randomized into Group 1 or Group 2. Patients will then undergo the procedure as described below.

Description of Procedures Being Performed

There are two procedures possibly being performed. In terms of the ECV, all patients will undergo an ultrasound examination as is necessary to confirm the malpresentation of the fetus and rule out any anomalies that would complicate a vaginal delivery. If found to have malpresentation patients will be placed on a fetal monitor and isotonic solution will be administered via IV. A CBC and type and screen will be drawn and sent. The patient will then be consented for the external cephalic version,as this is the procedure that the patient has come to the hospital for, and will be performed regardless if they participate in the study. After this, they will be asked if they would like to participate in a study. If so, a member of the research team will approach the patient and consent the patient for the study. If the patient consents and is randomized to Group 1, the patient will have a spinal administered by the on call anesthesiologist using standard protocol (intrathecal bupivacaine 7.5 mg). The patient will then be administered 0.25 mg Terbutaline subcutaneously and the ECV will be attempted. Under ultrasound guidance the provider will attempt to lift the breech upward from the pelvis with one hand and guide the head with the other hand to produce a forward roll. If forward roll fails, a backward roll somersault may be attempted. ECV attempt will be abandoned if there is significant fetal bradycardia, discomfort to the patient, or if the procedure cannot be completed easily with these maneuvers. Once attempt is complete, whether successful or not, the patient will be monitored for a minimum of 30 minutes, and will be discharged once they are able to walk, void, and tolerate PO intake, only if fetal and maternal status is reassuring. If the patient is randomized to Group 2, the patient will be administered terbutaline 0.25 mg subcutaneously and the version will be attempted using the same procedure as above. If successful, the patient will be monitored for 30 minutes and discharged if fetal and maternal status is reassuring. If the attempt fails, the patient will be administered spinal anesthesia as above and the same maneuvers will be attempted. Once attempt is complete, whether successful or not, the patient will be monitored for a minimum of 30 minutes, and will be discharged once they are able to walk, void, and tolerate PO intake, only if fetal and maternal status is reassuring.

Description of the Source Records that Will Be Used to Collect Data About Subjects

In order to collect data about the procedure, a member of the research team will fill out a questionnaire at the time of procedure and all questionnaires will be placed in a locked cabinet in the PI's office in Mount Sinai West- Suite-10C. All other data about delivery and demographics will be collected after the procedure using labor and deliveries' electronic medical record system (Peribirth).

Description of Data that Will Be Collected Including Long-Term Follow-Up

Protected Health Information (PHI) will be collected and used in the study. No PHI will be disclosed. Only study personnel will have access to subject information. The study investigators will collect medical information about the subject over the course of the study. Study data will be entered into a de-identified research secure password-protected database, using a unique code numbering system. A code number linked to subject identity will be used instead of names. The code number will not be derived from any patient identifiers, such as patient name or medical record number. The record linking the subjects' name with their assigned codes will be kept on a password protected file on a secure departmental drive. Only the PI will have access to this file. All study forms will be kept private and stored in a locked file cabinet in a secure location in the office of the PI. The secure computerized research database will be on a password-protected file within the OB/GYN department at Mount Sinai West. The linked code and dates of service are the only patient identifiers to be collected onto the computerized database spreadsheet along with the subject's medical information needed for the purposes of the study. Once data collection and analysis is completed, the linked code and data will be deleted.

Research Requires HIV Testing

13. Procedures - Genetic Testing

Genetic Testing Will Be Performed No

14. Procedures - Details

Surveys or Interviews Yes

Type of Instruments Being Used Created By Research Team

Description of Instruments Created By Research Team

The research team has created a questionnaire that will be filled out by the person performing the procedure once the procedure is completed. This questionnaire will then be collected by the PI and stored in a locked cabinet in the PI's office.

Audio / Photo / Video Recording No

Deception No

Results of the Study Will Be Shared with Subjects or Others No

15. Procedures - Instruments

Instruments Created By Research Team

Type	Questionnaire
Name	Questionnaire
Upload	Study form.docx

16. Procedures - Compensation

Compensation for Participation No

17. Consent - Obtaining Consent

Consent Process Adult Consent

Where and When Consent Will Be Obtained

External cephalic versions are scheduled each day by the patients' primary obstetrician. If a patient is found to be eligible for the study, an investigator will approach the patient once they are admitted for their external cephalic version on labor and delivery. A member of the research team will then review the consent with them. The investigator will give the potential subject the opportunity to ask any questions and have them answered. They will be given the opportunity to think about the study. (Only those investigators listed as study personnel and authorized to obtain consent, will obtain informed consent). Once a patient wishes to join the study and informed consent is obtained, the subject can participate. Each subject will receive a signed copy of the consent form. The subject can withdraw from the study at any time without any retribution.

Waiting Period for Obtaining Consent

The patient will be given as much time as they need to consider consenting for the study. Each patient that is admitted for an external cephalic version is placed on the fetal monitor and given 1-2 liters of isotonic solution prior to the procedure (this is routine at our institution). They will be given that amount of time (usually 30 minutes-1 hour) to decide if they would like to take part in the study. If they need more time, then we will wait until the patient has felt that they have had adequate time to decide if they would like to participate.

SOP HRP-090 Informed Consent Process for Research Is Being Used Yes

Process to Document Consent in Writing Will Use Standard Template

Non-English Speaking Participants Will Be Enrolled Yes

What Languages Other Than English Will Be Used

Any language can be used as long as an approved interpreter is available for that language at the time of consent. We will follow the Short Form Policy regarding proper consent and interpreters.

What Process Will Be Used Short Form

Attest that you will follow the Short Form Policy ([insert link]), including the Hospital policy (A3-105 at ISMH and HHC Administrative Policy ADM 30 at Elmhurst/Queens) regarding approved interpreters.

18. Consent - Documents

Consent Documents

Type	Consent
Name	Consent
Upload	Consent2(unmarked).doc

19. Data - Collection

Health Related Information Will Be Viewed, Recorded, or Generated Yes

Description of Health Information That Will Be Viewed, Recorded, or Generated

Primary outcome data to be collected includes: successful external cephalic version. Other information that will be recorded includes: name, MR #, ultrasound findings, patient pain score (1-10) from procedure, score for ease of performing the procedure, complications from procedure, delivery mode, 5 minute, Apgar score <7, arterial cord pH <7.2, NICU admission. Demographic data will also be collected such as age, race, BMI, parity, and medical disease.

Non-Health Related Information Will Be Viewed or Recorded No

HIV / AIDS Related Information Will Be Viewed or Recorded No

Data That Will Be Viewed, Recorded, or Generated Contains ANY of the Following Directly Identifiable Information Yes

Will Be Viewed Name, Medical Record Number

Will Be Recorded Name, Medical Record Number

Data Collection Sheet

A Data Collection Sheet is required if you are either performing a retrospective review, or your study meets the category of exempt 4 research, or your study meets the category of expedited 5 research. Please upload it here.

Data Collection Source(s) Participant, Medical Chart (Paper or Electronic)

20. Data - HIPAA

Obtaining HIPAA Authorization Yes

How PHI Will Be Protected from Improper Use or Disclosure

Protected Health Information (PHI) will be collected and used in the study. No PHI will be disclosed. Only study personnel will have access to subject information. The study investigators will collect medical information about the subject over the course of the study. Study data will be entered into a de-identified research database, using a unique code numbering system. A code number linked to subject identity will be used instead of names. The code number will not be derived from any patient identifiers, such as patient name or medical record number. The record linking the subjects' name with their assigned codes will be kept on a password protected file on a secure departmental drive. Only the PI will have access to this file. All study forms will be kept private and stored in a locked file cabinet in a secure location in the office of the PI. The computerized research database will be on a password-protected file within the OB/GYN department at Mount Sinai West. The linked code and dates of service are the only patient identifiers to be collected onto the computerized database spreadsheet along with the subject's medical information needed for the purposes of the study. Once data collection and analysis is completed, the linked code and data will be deleted.

PHI Will Be Destroyed at the Earliest Opportunity Consistent with the Research Yes

When and How PHI Will Be Destroyed

The files containing the data and linking files (containing PHI) will be deleted once all data has been analyzed. This will likely be approximately within 1 year of study completion.

PHI Will Be Shared No

PI must attest to the following. * I assure that the protected health information (PHI) will not be disclosed to any other person or entity not listed on this form except where required by law or for the authorized oversight of this research project. If at any time I want to reuse this PHI for other purposes or disclose it to other individuals or entities I will seek approval from the IRB.

21. Data - Storage

Location Where Data Will Be Stored

The research data file is stored on a secure "departmental" network drive and the file will be password protected.

How will the data be stored?	With a Code That Can Be Linked to the Identity of the Participant
Research Personnel Responsible for:	Natalie Porat
Accessing Data	Yes
Receipt or Transmission of Data	Yes
Holding Code That Can Be Linked to Identity of Participants	Yes
Research Personnel Responsible for:	Lois Brustman
Accessing Data	Yes
Receipt or Transmission of Data	Yes
Holding Code That Can Be Linked to Identity of Participants	No
Research Personnel Responsible for:	Barak Rosenn
Accessing Data	Yes
Receipt or Transmission of Data	Yes
Holding Code That Can Be Linked to Identity of Participants	No
Research Personnel Responsible for:	Zainab Al-Ibraheemi
Accessing Data	Yes
Receipt or Transmission of Data	Yes
Holding Code That Can Be Linked to Identity of Participants	No
Research Personnel Responsible for:	Dyese Taylor
Accessing Data	Yes
Receipt or Transmission of Data	Yes
Holding Code That Can Be Linked to Identity of Participants	No
Research Personnel Responsible for:	Migdalia Saloum
Accessing Data	Yes
Receipt or Transmission of Data	Yes
Holding Code That Can Be Linked to Identity of Participants	No
Research Personnel Responsible for:	Julio Marenco
Accessing Data	Yes
Receipt or Transmission of Data	Yes
Holding Code That Can Be Linked to Identity of Participants	No
Research Personnel Responsible for:	Jason White

Accessing Data	Yes
Receipt or Transmission of Data	Yes
Holding Code That Can Be Linked to Identity of Participants	No

Duration Data Will Be Stored

Data will be stored until the data is analyzed, within 1 year from study completion.

Steps That Will Be Taken to Secure the Data During Storage, Use, and Transmission

The study investigators will collect medical information about the subject over the course of the study. Study data will be entered into a de-identified research database, using a unique code numbering system. A code number linked to subject identity will be used instead of names. The code number will not be derived from any patient identifiers, such as patient name or medical record number. The record linking the subjects' name with their assigned codes will be kept on the computer in a separate secure folder. All files are password protected on a secure server.

Data Analysis Plan Including Any Statistical Procedures

Continuous variables will be analyzed using two tailed T-test and categorical variables will be analyzed using Pearson Chi Square test. Logistic regression will be used to adjust for confounders. A p-value <0.05 will be considered significant.

22. Data - Safety Monitoring

More Than the Minimum Data Safety Monitoring Will Be Done No

The following minimum requirements apply to all projects, including retrospective reviews of medical records, use of tissue samples, and many minimal risk studies, such as observational and survey research. Because these minimum requirements apply to all studies, a specific written DSMP will not usually be required for projects that do not pose greater than minimal risk to subjects. The MSSM PPHS may alter the required level of monitoring if appropriate. For all projects, the principal investigator must have a plan to assure that data integrity will be maintained during its collection, storage and analysis. All research projects must adhere to MSSM recommendations on the storage of research data. Loss of data containing identifiable information is reportable to the IRB within 5 business days. Any problems concerning the consent process and any subject complaints should be monitored by the investigator. Reports of such problems must be made at least annually. The discretion of the protocol director will guide the need to report these problems immediately or more frequently. The principal investigator is, typically, the monitoring entity for the minimum DSMP. When a principal investigator is not a faculty member, the supervising faculty member must be responsible for the data and safety monitoring aspect of the protocol.

23. Financial Administration

This information will help the Financial Administration of Clinical Trials Services (FACTS) office determine whether a Medicare Coverage Analysis (MCA) is needed for the research study. If you have any questions while completing this form, please contact the FACTS office at (212) 731-7067 or FACTS@mssm.edu.

Clinical Research Study Category Investigator Initiated

Payment Options: * Option 1: No protocol-required services will be billed to patients or third-party payers. Does Not Need MCA * Option 2: Protocol-required services (i.e., routine care services) will be billed to patients or third-party payers. Must Have MCA * Option 3: Study is initiated and federally funded by a Government Sponsored Cooperative Group who will only pay for services that are solely conducted for research purposes and other protocol-required services (i.e., routine care services) will be billed to patients or third-party payers. Billing Grid Only Required, NO MCA * Option 4: Study involves only data collection and has no protocol-required clinical services. Does Not Need MCA * Option 5: Study is not described in any of the above options. Please describe the study and specify whether External Sponsor (i.e., industry, government, or philanthropic source) and/or patient/third party payer will pay for protocol required services. MCA MAY Be Required

Payment Option Option 1

No MCA is needed per option selected above.

Payment Option 1: * Option 1A: Department/collaborating departments will act as internal sponsor paying for all protocol-required services and no protocol-required services will be billed to patients or third party payers. * Option 1B: Study involves protocol-required clinical services and an External Sponsor (i.e., industry, government, or philanthropic source) will pay for all protocol-required services.

Payment Option 1 Option 1A

24. Attachments

Type	Name	Version	Status	Filename	Uploaded Date
Instruments	Study form.docx	1	New	Study form.docx	12/21/2016
Consent Documents	ECV Consent-1.doc	1	New	Consent2(unmarked).doc	02/09/2017