NCT04836702

PROTOCOL

Background

1. Provide the scientific background, rationale and relevance of this project.

INSTRUCTIONS

- This should include a referenced systematic evidenced-based review when possible.
- If this study involves qualitative research explain the major constructs of your study.
- Do not state in this section what you plan to do in this study. This information should be entered later under "What will be done in this protocol?"
- Do not include the bibliography in this section.
- For studies submitted under the Expedited review criteria, this section need not be more than a few paragraphs.
- For those studies where data will be analyzed collaboratively by multiple sites doing a similar study for which there is no common protocol (Collaborative Site Analysis Study) include a description of the common scientific goals/ procedures/data points.
- If this is a FIVE YEAR UPDATE make sure the information throughout the protocol includes the most current information.

Answer/Response: Given the current culture of value driven healthcare with a focus on quality and cost, it's more important than ever to provide the most efficient and effective care to our patients.

Vascular surgery cases are among the most complex operations performed and its patients often have multiple comorbidities. As a result, quality improvement and monitoring of trends represent a critical opportunity for improvement. As we move into future value based purchasing driven by third party payers we will be required to provide the highest quality of care, by standard metrics, at the lowest cost. Identifying trends in complications and correlating these with standard outcome metrics will highlight areas of value improvement.

While many of the factors predicting poor outcomes are not modifiable, there are areas of improvement in practice at UVA. We will strive to identify patients at risk for post-operative complications and optimizing medical management of these comorbidities.

In a time of quality improvement and large data sets it is crucial to keep our university and department of surgery on the forefront of this research endeavor. As a leading academic medical center, other centers look to us to find evidenced based solutions to provide the highest quality care at the best value. For this reason we must constantly examine, analyze, and evaluate our experience and develop standard metrics to grade our outcomes and identify areas for improvement. As leaders in the field it is our responsibility to look beyond 30-day outcomes and determine the long-term impact of these operations using every resource at our disposal. Additionally, to determine true healthcare cost we must evaluate not only charges but calculate total cost and resource utilization.

Objectives/Hypothesis

INSTRUCTIONS:
If this study involves biomedical research clearly state the objectives and hypotheses and clearly define the primary and any secondary outcome measures. If this study involves qualitative research clearly state your research hypothesis or question.

This section should not include information already included in other sections such as background information or information from the procedures section.

Answer/Response:
We hypothesize there are modifiable risk factors and practice patterns that once optimized will allow improvement in care of vascular surgery patients evidenced by short term and longer term outcomes in addition to assessment of value of care.

Human Participants

INSTRUCTIONS: The Age/ Sex/ Race criteria should designate the demographics of subjects from whom you will obtain the specimens/data.

Age: __≥18__
Sex: __male and female__
Race: _any___
Number of Subjects at UVA protocol sites:

INSTRUCTIONS: Insert an exact #. Ranges or OPEN is not allowed. This # should be the maximum # you expect to need to enroll (i.e. sign consent) If you are not obtaining a consent the number should designate the number of subjects whose medical records you plan to review and or number of specimens you plan to obtain. Age/ Sex/Race criteria should designate the demographics of participants from whom you will obtain the specimen/data.

Answer/Response: 30,000

Inclusion/Exclusion Criteria

INSTRUCTIONS:

- The inclusion and exclusion criteria should be written in bullet format.
- *This item applicable if the study will require consent (verbal or written).* Unless there is a scientific reason for not recruiting a certain type of vulnerable population(e.g. not enrolling fetuses, neonates or children in a study regarding Alzheimer's) list the following vulnerable populations under either Inclusion or Exclusion criteria below: pregnant women, fetuses, neonates, children, prisoners, cognitively impaired, educational or economically disadvantage, non- English speaking subjects .
- If you will not enroll subjects who do not speak English because certain procedures cannot be carried out if the subject does not speak English (e.g. a survey is not validated in other languages) insert the following as an Inclusion Criteria: Willingness and ability to comply with scheduled visits and study procedures.
- If this is a collection of only retrospective* specimens or data, the inclusion criteria must include a start and stop date for when specimens/ data will be collected.
- The stop date must be prior to the version date of this protocol.

- *Retrospective: all specimens are in a lab at the time this protocol is approved by the IRB. All data exists in medical records or records from previous studies at the time this protocol is approved by the IRB.

1. List the criteria for inclusion

Answer/Response: All adult vascular surgery patients at UVA between 01/01/1990 and 07/17/2018.

2. List the criteria for exclusion

Answer/Response: Prisoners and individuals under the age of 18 years old.

3. List any restrictions on use of other drugs or treatments.

Answer/Response: N/A

Plan for Statistical Analysis

1. What are your plans for the statistical analysis?

INSTRUCTIONS: Include when appropriate how sample size was determined, and statistical methods to compare groups for primary outcome(s) and additional analyses.

Answer/Response: Univariate and multivariate analysis

Study Procedures- Chart Review- Data to be Collected

1. Describe the data that will be collected.

Answer/Response: All demographic, preoperative medical/comorbidity, intra-operative data, post-operative complications and statistics, hospital cost/resource info, diagnoses, procedures, laboratory, medications, clinical parameters, and longer term survival using Social Security data. We will use demographic data to look at distance traveled to UVA and socioeconomic status. We will use billing data to look at cost and resource utilization.

2. Will you be using data/specimens in this study that were collected previously, with the use of a research consent form, from another research study?

Answer/Response: No

IF YES, will the data/specimens be used in this study without a new consent from the original donor?

Answer/Response:

IF YES, explain how the proposed use is consistent with the use planned in this study and submit a copy of the consent form used to collect the data/specimens.

Answer/Response:

INSTRUCTIONS: If you are unable to locate the consent form, you must request a Waiver of Consent. Consult with IRB staff to determine additional sections to be added to this protocol.