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TITLE: Application of Near Infrared Spectroscopy, Intravascular Ultrasound and the Coronary Calcium Score to Predict Adverse Coronary Events

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Fort Detrick, Maryland 21702-5012

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12. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

A total of 1126 patients were screened for inclusion in the trial. A total of 55 patients were enrolled and completed initial invasive evaluation. The last of these was enrolled on September 22, 2016. The initial trial design calls for 5 year follow-up to adjudicate clinical events. A request to continue patient follow-up to 5 years by extending the study was not granted. Five year follow-up for the first patient enrolled (6/9/14) will occur in 2019. Interim events have occurred to date in only 9 patients with only one death. No relationship to any study variable can be made with such a low event rate on preliminary follow-up date. Funding for continued data collection for all enrolled patients to the 5 year end point is being sought locally.

15. SUBJECT TERMS

coronary artery disease, near infrared spectroscopy, calcium scoring, intravascular ultrasound

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
Unclassified	Unclassified	Unclassified	Unclassified	7	19b. TELEPHONE NUMBER *(include area code)*

Table of Contents

Page

Introduction

The aim of the present project is to

1. Utilize near infrared intra-coronary spectroscopy as an adjunctive technique during cardiac catheterization to identify potential vulnerable plaque morphology
2. Relate its presence to intermediate and long-term outcomes in patients defined as angina, myocardial infarction, death, congestive heart failure, stroke and need for revascularization over five years.
3. To compare near infrared intra-coronary spectroscopy data to that from coronary calcium scoring, angiographic findings and intracoronary ultrasound in predicting those outcomes in #2.

Keywords

coronary artery disease, intravascular ultrasound, near infrared spectroscopy, calcium scoring

Accomplishments

The original award in 2011 was revised under the direction of scientific officers several times. Patient recruitment began in 2014 after final approval by all involved. Subsequently, 1126 patients were screened for inclusion in the trial.

The first patient was enrolled on 6/9/2014. The initial protocol was designed for five year follow-up to allow adequate statistical power. Thus, five-year follow-up for the first patient enrolled would occur in 2019.

Successful enrollment of 55 patients with coronary angiography, coronary calcium scoring, intravascular ultrasound examination, and near infrared spectroscopy was accomplished.

Follow-up of all enrolled patients as of December 2016 (end of study) has revealed only nine interim events. Only one of these was a cardiovascular death. Thus, no relationship to any study variable can be made at this early date.

Event rate in this patient cohort has proven to be exceedingly low at the midpoint in planned five year follow-up. No significant nine relationship between any anatomic variable can be made with only one patient having a significant cardiovascular event in follow-up. Thus, data are negative at this point, however, continued local follow-up is planned pending funding.

Impact

Successful application of simultaneous coronary angiography, intravascular ultrasound, and near infrared spectroscopy in a significant number of patients undergoing elective cardiac evaluation is significant. This represents an ambitious invasive strategy for evaluation which has been accomplished in this study with no significant complications. This will have impact in applying such methodologies to further pathophysiologic study in humans.

Changes/Problems

None

Products

No significant products were involved in this study.

Participants and other collaborating organizations

No other collaborating organizations were involved in the study. Participants included Dr. Charles Lambert (PI), Janice Shirley (administration), Dr. Brian Nordgren (physician's assistant and research coordinator), and part time participation by covering research coordinators. Coinvestigators listed at a local IRB level included attending physicians referring patients for study.

Special reporting requirements

None

Appendices

IRB final report:

FLORIDA HOSPITAL
PEPIN HEART INSTITUTE
Dr. Kiran C. Patel Research Institute
The skill to heal. The spirit to care.®

Investigator's Progress Report

Continuing Review / Interim Report /
Final Report of Research

Florida Hospital Tampa Bay Division IRB

Full Board Continuing Review Instructions:	Expedited Continuing Review Instructions:
Submission deadline: All Part A & B documents due on the 1st of the month for review on the 3rd Tuesday. All documents are to be submitted under (2) separate Part A & B email attachments or 17 collated paper copies. Ensure all documents and revisions are clearly identified, *and in the following order:*	If ☐ the protocol is permanently closed to the enrollment of new participants, ☐ all participants have completed all research-related therapy / interventions (labs, x-rays, etc.), and the ☐ research remains active only for long-term follow-up of participants; -OR- ☐ No participants have been enrolled and no additional risks have been identified; -OR- ☐ The remaining research activities are limited to data analysis only; your continuing review *may* be eligible for Expedited Review (45 CFR 46.110). ***Expedited submissions may be submitted at any time via Email or 3 paper copies to the IRB.***

Final Report Instructions: If the project is complete*, submit this form and check "Final Report - Termination Requested". *The form must be completely filled out, and any publications and/or data analysis reports included with the submission.*

Part A ☒ #1.	- Continuing Review Application filled out completely, and signed. *Please note that blanks and/or insufficient information may result in a delay of your review/approval.*

Contact Information

Today's Date: *31OCT2016*	Date of Initial Review: *17JUL2012*	Date of Last Continuing Review: *05MAY2016* Date Last Seen by the IRB: *17JUN2016*	
Type of Submission:	☐ Continuing Review	☐ Interim Report	☒ Final Report – Termination requested
Type of Review Requested:	☒ Full Review	☐ Expedited Review	
Protocol Information:	Title: ***Proposal 10169004 - Application of Near Infrared Spectroscopy, Intravascular Ultrasound and the Coronary Calcium Score to Predict Adverse Coronary Events***		
	Protocol #: *5/2012*	Protocol Version (current): *5/2012*	
Study Type:	☐ Device	IDE #:	Phase#:
	☐ Drug	IND #:	Phase #:
	☐ Post Market Approval Study	☐ Registry	☒ Prospective Data Review / ☐ Retrospective Data Review
	☒ Investigator Initiated Study *Please describe type of trial:		
	☐ Other (please describe):		
Principal Investigator:	*Charles Lambert, MD, PhD MBA*		
Primary Contact:	*Kiara Touros, MS*	E-mail:	*Kiara.Touros@ahss.org*
Telephone:	*(813)615-7200 ext. 50321*	Fax:	*(813)615-7574*

Current Status of Project (check only one):

Part A ☒ #2.	Please summarize activity for all study types. **For data review studies, summarize the number of charts, etc, that were reviewed.*

* No participants on therapy or in follow-up, no data collection being done, and no data queries being resolved.