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W81XWH-10-2-0133

TITLE:
Treatment of Early Post-Op Wound Infection after Internal Fixation

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14. ABSTRACT Postoperative infection is one of the most prevalent and challenging complications faced by orthopaedic surgeons and patients in both the military and civilian populations. The wounds are contaminated or colonized at the time of injury, during the course of therapy, or both. Infection is always a possibility with any surgical intervention, particularly in the setting of orthopaedic trauma where multiple factors make the prevention and treatment of these infections very complicated. As of October 1, 2018, a total of 2028 patients have been screened for eligibility, and of these, 905 (45%) were eligible. Of the 905 eligible patients, 232 (26% of eligible) were consented and enrolled into the RCT; 130 (14% of eligible) were consented and enrolled into the observational arm. As of October 1, 2018, the study has been closed for enrollment and we reached 87.9% of our total enrollment. Two hundred and fifteen of all patients have completed the study.					
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**Annual Report: “Treatment of Early Post-Op Wound Infection after Internal Fixation”
Sept. 15, 2017 - Sept. 14, 2018**

Introduction:

Severe fractures are common in modern warfare with fractures being fixed via internal fixation of plates and screws to hold the fracture stable while the bone heals. Approximately 10%-40% of severe fractures fixed with internal fixation develop a deep wound infection during the healing process. Thus, the overall goals of this study are to investigate the efficacy of oral (per os, (PO)) antibiotic therapy versus intravenous (IV) antibiotics in the treatment of acute infection after fixation of fractures or fusion of joints.

Study Specific Aim # 1: To evaluate the effect of treatment of post-op wound infection in bones after fracture fixation or joint fusion and either: (Group 1) operative debridement and PO antibiotic treatment for 6 weeks; or (Group 2) operative debridement and IV antibiotics for 6 weeks.

Study Specific Aim # 2: To build and validate a risk prediction model for failure of treatment of early post-op wound infections after fixation of fractures and joint fusions.

Body:

During the current reporting period, the Principal Investigator (PI) focused on administrative tasks essential to recruitment and enrollment into the study. As of October 1, 2018, a total of 2028 patients have been screened for eligibility, and of these, 905 were eligible. Of the 905 eligible patients, 232 (26% of eligible) were consented and enrolled into the RCT; 130 (14% of eligible) were consented and enrolled into the observational arm. As of October 1, 2018 the study has been closed for enrollment and we reached 87.9% of our total enrollment. Two hundred and fifteen patients have completed the study.

Task 1	Months 1-6	Completed
Task 2	Months 6-72	Completed
Task 3	Months 12-84	Completed
Task 4	Months 48-84	Complete Follow up visits- in progress
Task 5	Months 84-96	Conduct analysis and final report- in progress

NEXT STEPS:

- Begin data quality close out reports and data cleaning for each site
-
- Complete follow up visits by September 2019.
- Begin data analysis
- Develop reports related to project deliverables for Consortium

Key Research Accomplishments:

- We reached 87.9% of our enrollment goals
- 215 patients have completed the study
- The implementation of the observation arm increased our overall enrollment rate.

Reportable Outcomes:

There were 24 serious adverse events (SAEs) reported during this reporting period. One SAE was due to death. Nineteen events were related to abnormal laboratory results and each determined by the medical monitor to be unrelated to study participation. The remaining four consisted of anemia, kidney failure, hospital admission for worsening of infection, and pneumonia.

The medical monitor reviewed all SAEs and determined that no further action was required.

Conclusion: None

References:

None

Appendices:

Quad Chart

Treatment of Early Post-Op Wound Infection after Internal Fixation

OR090346

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PI: William Obremesky, MD MPH

Org: Vanderbilt University Medical Center

Award Amount:\$2,972,205

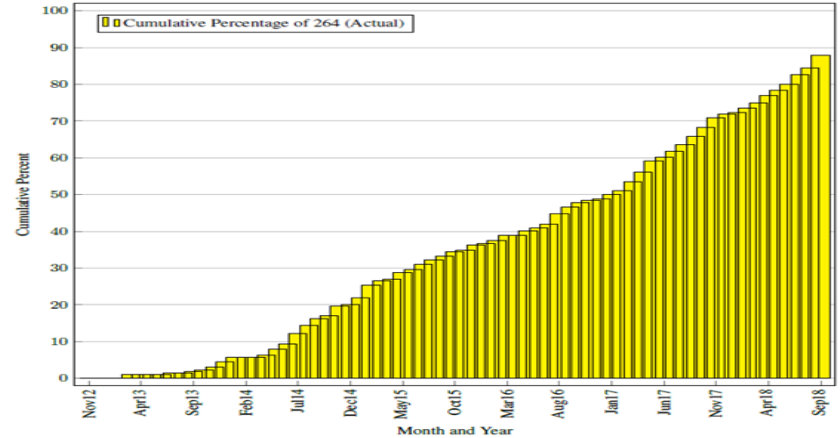
Study/Product Aim(s)

- PO antibiotics efficacy equal to IV antibiotics
- PO and IV antibiotic bioavailability is similar
- Development high level evidence to inform clinician choices regarding post operative infections and potentially inform practice changes

Approach

We will compare PO vs IV antibiotics in patients with infections of internal fixation of fractures/ fusions. Patient will be monitored for Infection recurrence, amputation, line sepsis and other complications.

Cumulative Enrollment



Study is now closed for enrollment. We completed 87.9% of our total RCT enrollment with 232 patients in RCT. Also 130 were enrolled in the observational study. Follow Up continues with 215 patients have completed study.

Timeline and Cost

Activities	CY	11-12	13-14	15-16	17-18
Active enrollment		[Green bar spanning 11-12, 13-14, 15-16, 17-18]			
Active Follow- up			[Green bar spanning 13-14, 15-16, 17-18]		
Data Analysis				[Green bar spanning 15-16, 17-18]	
Manuscript and Final Report					[Green bar in 17-18]
Estimated Budget (\$K)		\$400	\$650	\$600	\$600

(Updated: 10-26-18)

Goals/Milestones CY11 Goal – Finalize Study Protocol

- Train and Certify Staff
- CY12 Goals – IRB Approval**
 - Obtain DoD and local IRB approvals
- CY13 Goal – Initiate Patient Enrollment**
 - Data entry via REDCap, routine training of sites
- CY14 Goal – Continue Enrollment, Initiate Follow-up**
 - Quality reports to sites with request for missing data
- CY15 Goal – Continue Enrollment and Follow -up**
 - Quality reports to sites with request for missing data
- CY16Goal – Continue Enrollment and Follow -up**
 - Quality reports to sites with request for missing data
- CY17Goal – Continue Enrollment and Follow -up**
 - Quality reports to sites with request for missing data
- CY18 Goal – Complete Enrollment**
 - Complete Enrollment and begin data cleaning
 - Finish data cleaning and analysis, final report
- CY19 Goal – Complete Follow-up**
 - Finish data cleaning and analysis, final report

Budget Expenditure to Date \$2,547,770

Projected Expenditure:\$2,972,205

Actual Expenditure: \$2 547 770