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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 2058 patients have been screened for eligibility, and of these, 920 were eligible. Of the 920 eligible patients, 232 (25% 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, 2019, the study has been closed for enrollment and we reached 87.9% of our total enrollment. Two hundred and ninety two patients have completed the study.					
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**Annual Report: “Treatment of Early Post-Op Wound Infection after Internal Fixation”
Sept. 15, 2018 - Sept. 14, 2019**

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, 2019, a total of 2058 patients have been screened for eligibility, and of these, 920 were eligible. Of the 920 eligible patients, 232 (25% 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, 2019 the study has been closed for enrollment and we reached 87.9% of our total enrollment. 292 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:

- Distribute site close out reports and continue working with sites to clean data
- Begin data analysis
- Develop reports related to project deliverables for Consortium

Key Research Accomplishments:

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

Reportable Outcomes:

There were 2 SAEs reported since the last DSMB report. One of the new SAEs involved a patient with poorly controlled diabetes who developed an ulcer and deep infection that led to a below the knee amputation. The second SAE was a patient death of unknown cause. The medical monitor reviewed the events and determined both to be probably not related to study participation and indicated neither required further action

Conclusion: None

References:

None

Appendices:

Quad Chart