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

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14. ABSTRACT

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 (1) evaluate the effect of treatment of post-op wound infection in long 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 and (2) build and validate a risk prediction model for failure of treatment of early postoperative wound infections after fixation of fractures or joint fusion.

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Nothing Listed

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Annual Report: "Treatment of Early Post-Op Wound Infection after Internal Fixation"
Sept. 15, 2014 - Sept. 14, 2015

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 (1) evaluate the effect of treatment of post-op wound infection in long 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 and (2) build and validate a risk prediction model for failure of treatment of early postoperative wound infections after fixation of fractures or joint fusion.

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, 2015, a total of 634 patients have been screened for eligibility, and of these, 258 (41%) were eligible. Initial screening criteria for POvIV are all patients, age 18-84, inclusive, with long bone fractures or joint fusions, AND suspected to have a wound infection pending intra-operative cultures. Of the 258 eligible patients, 120 were enrolled in the study. Of the 120 patients enrolled, 88 were enrolled into the RCT and 32 were enrolled into the observational study. We have now reached 33.3% of our total enrollment. Twenty-six patients have completed the study.

Due to a lapse in cellular service and some difficulties working with Vitality, we decided to make the transition to using a different apparatus to monitor patient oral medication adherence. We are moving from using the Vitality GlowCaps to a different apparatus called the Medication Event Monitoring System (MEMS). With an electronic cap which automatically compiles drug dosing history in a web based system we be able to track medication adherence in a similar fashion as we did with the GlowCaps. The amendment including this adherence tracking change has been approved by the Johns Hopkins School of Public Health IRB and has been distributed to all the sites.

Task 1	Months 1-6	Completed
Task 2	Months 2-6	Completed
Task 3	Months 7-30	Roll out of enrollment – in progress
Task 4	Months 7-42	Enrollment ongoing
Task 5	Months 43-48	initiated

NEXT STEPS:

- Assist sites with facilitation of the approval of the amendment that changes our adherence technology to the MEMS cap.
- Train on coordinators on the use of the MEMS cap.
- Provide follow up support and guidance to the sites during implementation of the MEMS caps
- Encourage sites to schedule meetings Infectious Disease teams to review study and study roles
- Develop Reports related to project deliverables for Consortium

Key Research Accomplishments:

- We have completed over 33% of our enrollment goals
- Twenty-six patients have completed the study
- The implementation of the observation arm has increased our enrollment rate.

Reportable Outcomes:

There were 5 serious adverse events (SAEs) reported during this reporting period. All five events were related to abnormal laboratory results and each determined by the medical monitor to be unrelated to study participation.

Conclusion:
None

References:

None

Appendices:

None