Supplement 1: Protocol summary

PROPHYLACTIC ANTIBIOTIC THERAPY DURATION IN NON-OPERATIVE FACIAL FRACTURES

BACKGROUND: Approximately 3 million individuals suffer craniofacial trauma in the United States on a yearly basis, and approximately 50% of all wounds presenting to emergency rooms involve the head and neck [1, 2]. Prophylactic antibiotics have been employed to decrease infectious complications; however, up to 60% of antibiotics prescribed in the emergency department are inappropriate [3]. While indications for prophylactic antibiotic usage in facial fractures have been extensively studied, low overall data quality and sample size have limited the development of clinical practice guidelines [4-16]. The aim of this study is to establish the optimal duration of prophylactic antibiotics.

STUDY TYPE: Multicenter Prospective Observational Study

PRIMARY AIM: To determine if prophylactic antibiotics for 0-24 hours, 25-72 hours, or >72 hours for non-operatively managed facial fractures decreases the incidence of fracture-associated infections.

PRIMARY HYPOTHESIS: Frequency of infectious complications will be independent of antibiotic therapy duration.

SECONDARY AIM: To determine the incidence of antibiotic associated adverse drug events.

SECONDARY HYPOTHESIS: Patients with longer duration of antibiotics will have a greater incidence of adverse drug events.

INCLUSION CRITERIA: Patients with non-operative facial fractures ≥ 18yrs of age

EXCLUSION CRITERIA: Patients <18yrs of age, operative facial fractures, pregnant or lactating women, prisoners, pathologic fractures, immunocompromised patients, antibiotics for secondary purpose, or enteric injury at index admission

PROTOCOL: Three cohorts will be defined as 0-24 hours, 25-72 hours, or >72 hours of post-injury prophylactic antibiotic therapy. Fracture associated infections will be determined through a 30-day post discharge EMR review using the diagnostic criteria presented in Figure 1. Adverse drug events will be defined using criteria outlined in Figure 2. When possible inclusive EMR review (i.e. Care Anywhere) should be utilized.

DATA COLLECTIBLES: To be finalized and distributed prior to study initiation. Collectibles will include standard responses to improve reporting between centers.

Figure 1: Identification of fracture associated infectious complications

I. Signs of infection involving the head and neck
   - Localized swelling
   - Localized erythema
   - Purulent drainage

III. Antibiotics or a debridement/drainage procedure of the face, skull, brain, meninges, or neck

IV. Craniofacial abscess, sinusitis, osteomyelitis, cellulitis, meningitis, wound infections, **or** soft tissue infection(s)

Presence of any of the above conditions or diagnoses within 30-days of injury is considered positive for fracture associated infectious complication.

Figure 2: Identification of adverse drug events

I. *C. difficile* infection
II. Allergic reaction to antibiotic
III. Severe side effects requiring readmission

Presence of any of the above conditions or diagnoses within 30-days of injury is considered positive for adverse drug events.