

Category : **Hematology: bleeding\transfusion**

**A175 - The first-2 prospective, randomized study of clotting factor concentrates versus standard massive hemorrhage protocol in severely bleeding trauma patients**

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### **Introduction:**

Bleeding plus acute trauma coagulopathy (ATC) is a leading cause of in-hospital mortality in trauma. Patients with ATC are up to 8 times more likely to die  $\leq 24$  h after injury than those without coagulopathy. Acquired fibrinogen deficiency and impaired thrombin generation are major drivers of ATC. Prompt and targeted coagulation factor replacement with fibrinogen concentrate (FC) and prothrombin complex concentrate (PCC) may be superior to current standard of care with ratio-based plasma resuscitation via a massive hemorrhage protocol (MHP). FiiRST-2 is investigating whether FC+PCC given  $\leq 1$  h after hospital arrival is superior to standard of care.

### **Methods:**

FiiRST-2 is a randomized, parallel-control, superiority trial with an adaptive two-stage design, performed in eight Canadian Level One Trauma Centers. Bleeding trauma patients  $>16$  years old (N=350) receive FC+PCC or a minimum 2:1 red blood cells (RBCs):plasma transfusion plus platelets, until the second MHP pack has been given, MHP is terminated, or 24 h has elapsed from admission (Figure 1). Exclusion criteria include receipt of  $>2$  units RBCs before randomization,  $>3$  h elapsed from injury, catastrophic brain injury, or known congenital or acquired bleeding disorders. The primary endpoint is superiority in the number of composite allogeneic blood product units transfused  $\leq 24$  h after admission. Secondary endpoints include RBC units transfused  $\leq 24$  h after admission, ventilator-free days, and 28-day mortality. Adverse and serious adverse events, including thromboembolic complications, will be assessed through 28 days.

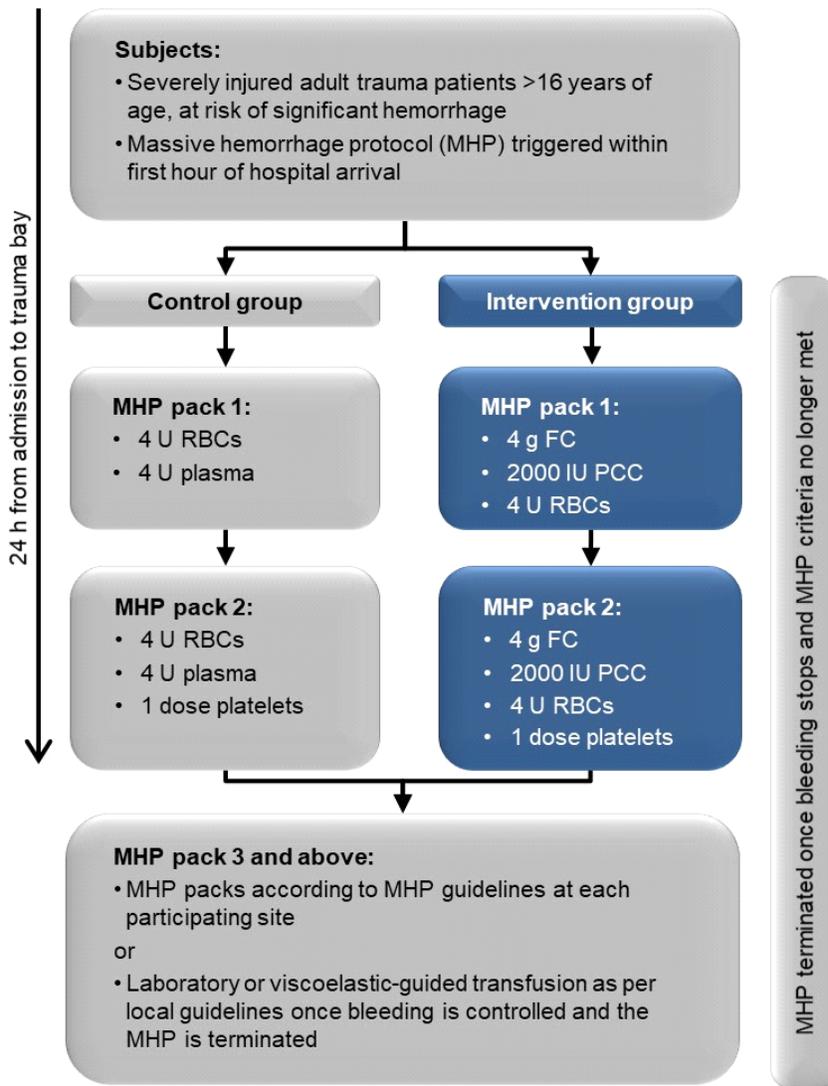
### **Results:**

FiiRST-2 has enrolled 3 patients at 1 site and is expected to complete in Q1 2023.

### **Conclusion:**

This study could have a major impact on clinical practice and improve the management and outcomes of bleeding trauma patients. FiiRST-2 will determine if early use of factor concentrates (FC+PCC) is superior to standard of care (ratio-based plasma resuscitation) in these high-risk patients.

**Image :**



FC = fibrinogen concentrate; PCC = prothrombin complex concentrate; RBC = red blood cells

Figure 1. Study treatment plan