Category :**Polytrauma**

A198 - ***Prospective, multicenter, randomized study comparing administration of clotting factor concentrates with a standard massive hemorrhage protocol in severely bleeding trauma patients***

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Introduction:

The FiiRST-2 study will investigate if fibrinogen concentrate (FC) + prothrombin complex concentrate (PCC) administered within the first hour of hospital arrival is superior to the current standard of care: blood component therapy via a massive hemorrhage protocol (MHP) in trauma patients. Hemorrhaging trauma patients may develop acute trauma coagulopathy, which has multifactorial etiology. However, acquired fibrinogen deficiency and impaired thrombin generation are becoming recognized as major drivers. Prompt and targeted coagulation factor replacement with FC and PCC may be superior to standard blood component therapy.

Methods:

FiiRST-2 is a multicenter (8 Canadian centers), pragmatic, randomized, parallel-control, superiority trial with an adaptive two-stage design. Trauma patients >16 years old at risk of massive hemorrhage will be randomized to receive FC + PCC or standard of care (1:1:1 red cell [RBC]:plasma:platelet transfusion) until after the second MHP pack has been administered, MHP is terminated, or 24 h from admission to the trauma bay (Figure 1). Exclusion criteria include receiving >2 U RBCs within 1 h post-admission, ≥3 h elapsed from injury, severe traumatic brain injury, or known congenital or acquired bleeding disorders. The primary endpoint is to demonstrate superiority with respect to the number of allogeneic blood product units (RBCs + plasma + platelets) transfused from admission to 24 h after admission. Secondary endpoints include RBC units transfused from admission to 24 h after as a surrogate for hemorrhage control. Safety endpoints include AEs and SAEs during 28 days after admission.

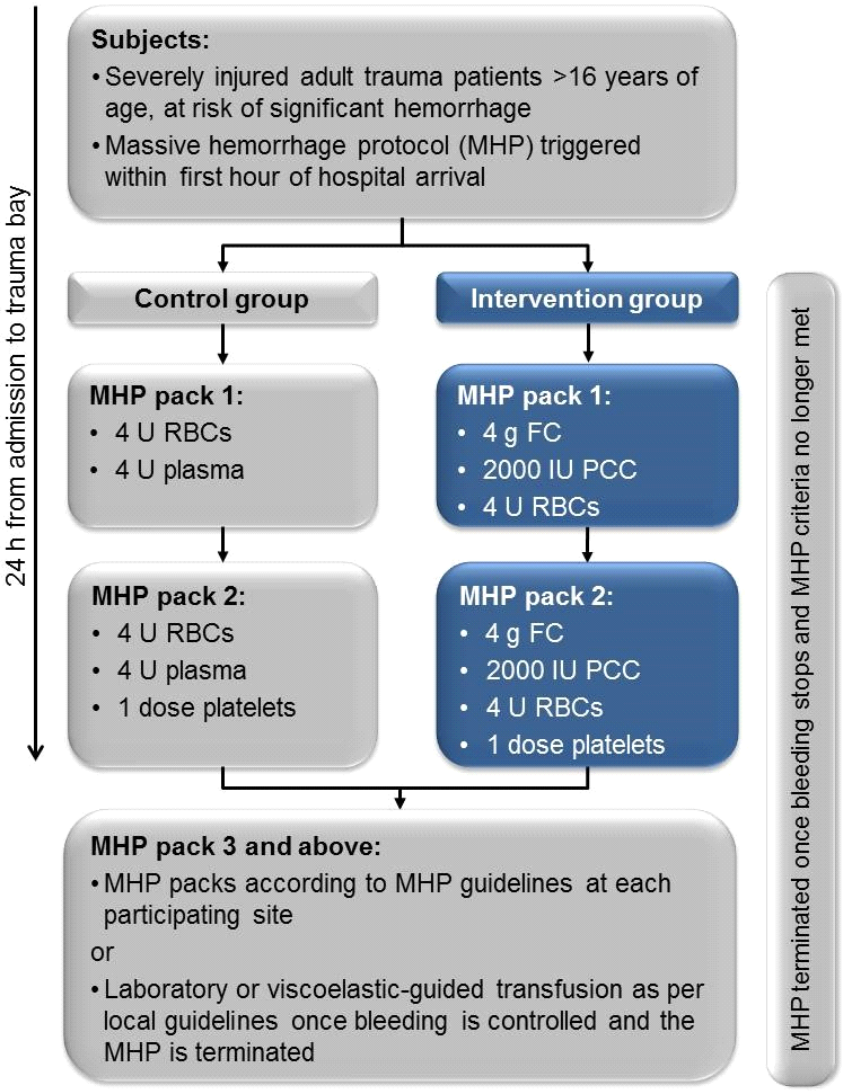
Results:

The study is expected to end Q1 2022.

Conclusion:

This pragmatic multicenter trial will determine if early hemostatic therapy with FC + PCC is superior to standard MHP packs in bleeding trauma patients. Results could have a major impact on clinical practice and improve the management and outcomes of this high-risk group of patients.

Image :



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

Figure 1 - Study Treatment Plan