Category :**Hematology: bleeding\transfusion**

A235 - ***The fiirst-2 prospective, randomized study of clotting factor concentrates versus standard massive hemorrhage protocol in severely bleeding trauma patients***

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Introduction:

The FiiRST-2 study will investigate whether fibrinogen concentrate (FC) and prothrombin complex concentrate (PCC) given ≤1 h after hospital arrival is superior to the standard of care in bleeding trauma patients. Bleeding coupled with acute trauma coagulopathy (ATC) is a leading cause of in-hospital mortality in trauma. Acquired fibrinogen deficiency and impaired thrombin generation are major drivers of ATC. Prompt and targeted coagulation factor replacement with FC and PCC may be superior to the current standard of care, a ratio-based plasma resuscitation via a massive hemorrhage protocol (MHP).

Methods:

FiiRST-2 is a randomized, parallel-control, superiority trial with an adaptive two-stage design, performed in 11 Canadian Level One Trauma Centers. Bleeding trauma patients >16 years old (N=350) will 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 bleeding disorders. The primary endpoint is superiority in the number of composite allogeneic blood product units transfused ≤24 h after admission. Secondary endpoints include RBC units transfused ≤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.

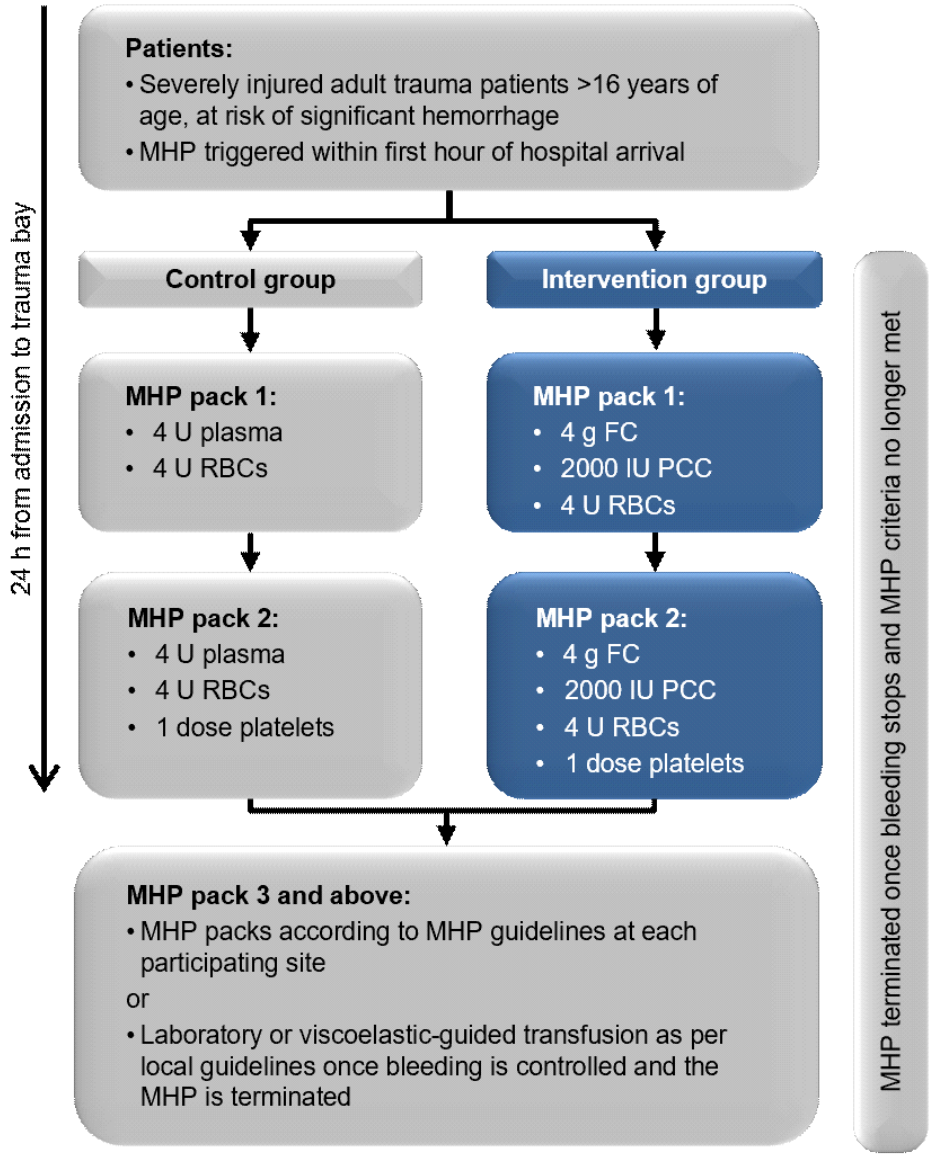
Results:

FiiRST-2 has enrolled 60 patients at 4 sites to date. An interim analysis will be performed after 120 patients have completed the study. Completion is expected in Q1 2023.

Conclusion:

The FiiRST-2 study will determine if early use of factor concentrates (FC+PCC) is superior to the standard of care in bleeding trauma patients. Results could have a major impact on clinical practice, improving management and outcomes for this high-risk patient population.

Image :



FC = fibrinogen concentrate; IU = international units;
MHP = massive hemorrhage protocol; PCC = prothrombin complex concentrate;
RBC = red blood cells

Figure 1: Study treatment plan