

Partial REBOA Outcomes Multicenter ProspecTive (PROMPT) STUDY SUMMARY

WHO?

INCLUSION CRITERIA:

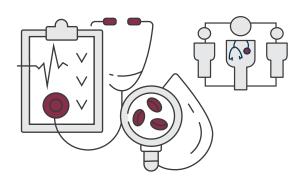
- ≥18 years or ≥ 50kg if age unknown
- Admitted at the highest activation level
- Treated with the pREBOA-PRO™ catheter

EXCLUSION CRITERIA:

- Prisoners
- Aged <18 years

Study Questions?

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INVESTIGATORS:

Total Study Goal 340 Subjects

Site Investigator

Andrew Beckett, CD MD MSc FRCSC FACS | General Surgery -Director of Trauma, SMH

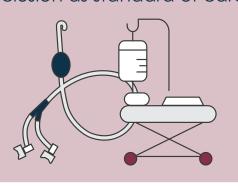
Principal Investigator

David Baer, PhD
CSO for Prytime Medical

WHAT?

STUDY DESIGN:

A multi-center prospective observational study of non-compressible torso hemorrhage (NCTH) patients being treated with the pREBOA-PROTM catheter for partial or full occlusion as standard of care.

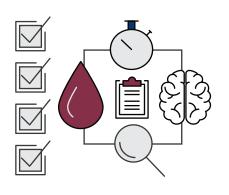


Key Study Questions

- 1. Does pREBOA-PRO™
 enable clinicians to
 perform partial REBOA in
 the emergent treatment
 of bleeding trauma
 patients?
- 2. Does partial REBOA provide clinical benefits such as decreased distal ischemia, extended safe occlusion time, improved hemodynamics during transition to and from occlusion, and reduced blood product use?

Key Endpoints

- 1. Time of occlusion
- 2. Ischemic markers
- 3. Tolerance to reperfusion
- 4. Blood product use In patients receiving complete REBOA versus partial REBOA



WHY?

The DoD is funding a clinical study on partial REBOA using pREBOA-PRO™ to assess its impact on treating patients with NCTH, one of the leading causes of preventable mortality.

WHERE?

SETTING/PARTICIPANTS:

The study will take place at up to 8 Level 1 Trauma Centers across North America.



WHEN?

Enrollment will be performed 24/7 and ongoing for 24 months from the first enrolled patient until 340 subjects are identified.

