

A clinical trial for septic shock with endotoxemia

ClinicalTrials.Gov: NCT03901807 • IDE# G090151

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Open-label confirmatory RCT of biomarker-guided blood purification in the US

Granted Medical Breakthrough Designation by FDA

35% Subject Enrollment Complete

Looking for Additional Sites!

Patient Selection

Septic Shock requiring Vasopressors

Organ Dysfunction
MODS >9 or SOFA >11

Endotoxin Activity
0.6-0.9

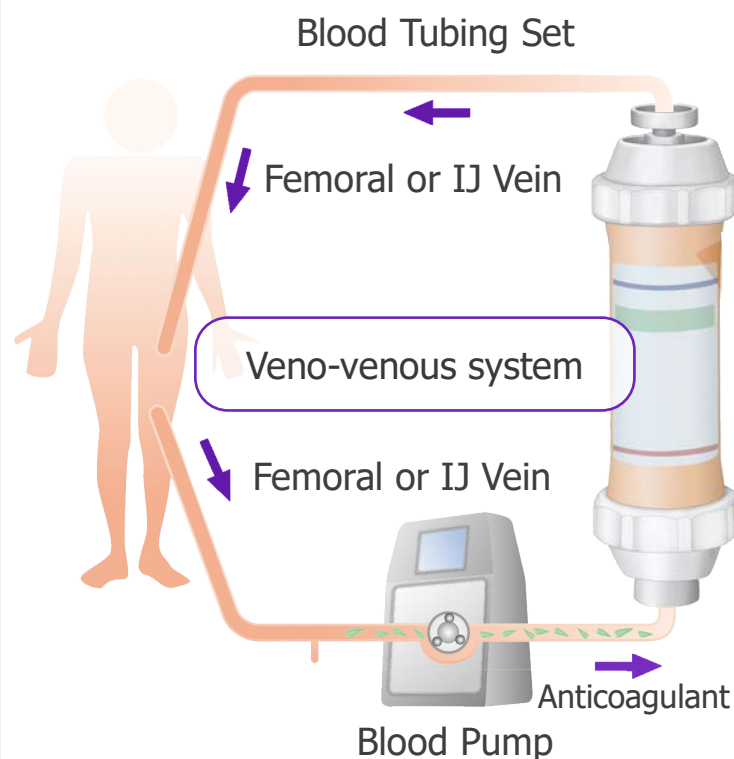
Randomization
2:1

Conventional Treatment and Monitoring
+
Two 2hr Toraymyxin™ Hemoperfusion Treatments (In 24 Hours)

Conventional Treatment and Monitoring

Treatment

PMX Treatment Duration:
2 hours



Perfusion Rate:
80-120 ml/min

Monitors inlet and outlet pressures

Primary Objective

Patient mortality at 28 days

Secondary Objectives

01

Change in Mean Arterial Pressure (MAP)

02

Change in vasopressor dose

03

Total duration of vasopressor use

04

Patient mortality at 14 days

05

Patient survival time from baseline

References

1. Endotoxemic Shock: A Molecular Phenotype in Sepsis. Nephron, Jul 2022. Pages 1-4. Kellum, J. A., Foster, D., & Walker, P. M.
2. Effect of Targeted Polymyxin B Hemoperfusion on 28-Day Mortality in Patients With Septic Shock and Elevated Endotoxin Level: The EUPHRATES Randomized Clinical Trial. JAMA, Volume 320, Oct 2018. Pages 1455-1463. Dellinger, R. P., Bagshaw, S. M., Antonelli, M., Foster, D. M., Klein, D. J., Marshall, J. C., Palevsky, P. M., Weisberg, L. S., Schorr, C. A., Trzeciak, S., Walker, P. M., & EUPHRATES Trial Investigators
3. Mechanisms of Organ Dysfunction in Sepsis. Critical care clinics, Volume 34, Jan 2018. Pages 63-80. Pool, R., Gomez, H., & Kellum, J. A.



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