Outcomes of Metabolic Resuscitation Using Ascorbic Acid, Thiamine, and Glucocorticoids in the Early Treatment of Sepsis.

ORANGES Trial

NCT#: NCT03422159

Study Design and Statistical Plan:

Study end-points:

Primary end-point

i. Time to vasopressor independence. Defined as the time from starting the active treatment/placebo to discontinuation of all pressors

ii. Delta SOFA score, defined as the initial SOFA score minus the day 4 SOFA score

Secondary end-points

iii. 28-day mortality

iv. Hospital mortality

v. PCT clearance (PCT-c) calculated using the following formula: initial PCT minus PCT at 96 hours, divided by the initial PCT multiplied by 100. [67,68]

vi. ICU mortality

vii. ICU length of stay (LOS) and ICU free days. ICU free days is calculated as the number of days alive and out of the ICU to day 28

viii. Hospital LOS

Data analysis:

Summary statistics will be used to describe the clinical data and presented as mean ± SD, median with interquartile range (IQR) or percentages as appropriate. Chi squared analysis with Fisher's exact test (when appropriate) and Student's t test (Mann Whiney U test for non- normal distributions) were used to compare data between the active treatment group and the placebo group with statistical significance

declared for probability values of 0.05 or less.