

VIT
VICTORY

Patient Eligibility

Screening

- + We think vitamin C will be less effective if initiated late in the course of burn patient treatment and will be most effective if initiated within 3-6 hours of arrival at your hospital, during the active phase of resuscitation. Randomization should occur as soon as possible following confirmation of eligibility.
- + If approved by your ethics committee we allow deferred or professional (impartial third party) consent in order to expedite the consent process (more on that in the next slide deck).

Screen and Randomized as soon as possible following admission to your Hospital!

Inclusion Criteria

1. Adult (≥ 18 years of age) at the time of consent
2. Deep 2nd and/or 3rd degree burns requiring skin grafting with a minimum of Total Body Surface Area (TBSA) burn $\geq 20\%$

TBSA and Grafting

We want to capture patients with large enough burns that they will require significant fluid resuscitation and are at risk for significant organ injury (potential primary endpoint). Therefore, we have set the minimum TBSA to $\geq 20\%$. There is nothing magical about 20% and given that burn sizes are approximate, we would encourage you to include a patient if you can justify that their TBSA is “approximately 20%”.

There is no minimum area that requires grafting. As long as the total burn size meets the inclusion criteria and a graft is required, the patient is eligible.

Thermal Burn Injuries

Patients enrolled in the VICToRY Trial must be diagnosed with a thermal burn injury. The table below outlines the types of burn injuries to include and which injuries or disease states not to include:

INCLUDE	EXCLUDE
Thermal burn injuries: <ul style="list-style-type: none">+ Scald+ Flame+ Flash+ Radiation+ Chemical+ Unknown+ Other, specify _____	Do NOT include injuries from: <ul style="list-style-type: none">+ High voltage electrical contact (without cutaneous burns that meet the inclusion criteria, however, if the cutaneous burns meet the inclusion criteria the patient is eligible and the burn type would be Flash)+ Frostbite+ Stevens-Johnson Syndrome (SJS)+ Toxic Epidermal Necrolysis (TEN)



Exclusion Criteria

1. > 24 hours from admission to ICU or burn unit to assessment.
 - + Most effective if initiated within 3-6 hours of arrival at your hospital during the active phase of resuscitation.
 - + **Want treatment to start as soon as possible!**
2. Patients admitted to burn unit > 24 hours from injury or accident.
 - + Significant delays to onset of vitamin C may diminish the effectiveness.
3. Patients who are moribund (not expected to survive the next 72 hours).
 - + Ask attending if high, moderate, or low probability of patient surviving the next 72 hrs. Enroll mod-high.

Exclusion Criteria

4. Pregnancy (pregnancy will be ruled out as part of standard of care) or lactating.
5. Enrollment in another industry sponsored ICU intervention study
 - + No need to request approval from CERU for observational trials.
 - + Send us abstracts/protocols of academic RCTs for approval.
6. Receiving high-dose IV vitamin C already (enteral or oral vitamin C is allowed).
 - + If it is your practice to use high dose vitamin C during the resuscitation phase you will need to delay or suspend this practice until the patient has been deemed ineligible for the VICToRY trial.

Exclusion Criteria

7. Known glucose-6-phosphate dehydrogenase (G6PD) deficiency.
 - + We expect this to be a rare circumstance but need to exclude them for safety reasons (vitamin C can cause hemolysis in these patients).
8. Recent history of kidney stones (within the last year).
 - + We expect this to be rare and what we are really looking for is oxalate acid kidney stones but since more people won't know what type of kidney stone, we will exclude anyone with a history of any kind of kidney stone in the last year as a safety precaution.

Questions

