# Adaptive Photoprotection Trial

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## Introduction

A growing body of literature has demonstrated a moderate negative correlation between vitamin D insufficiency and morbidity and mortality from Covid-19 infection[1]. Confounding this is the fact that serum vitamin D levels are also low in comorbidities that also correlate with higher Covid-19 mortality[2,3].

Vitamin D – and at least 30 other immunoregulatory compounds – is produced in response to ultraviolet B (UVB) light[1]. UVB light is standard of care in several autoimmune diseases, including graft vs. host disease, cutaneous T-cell lymphoma, and psoriasis[4,5,6]. To date, no studies have aimed to determine whether or not UVB phototherapy can improve Covid-19 outcomes[7].

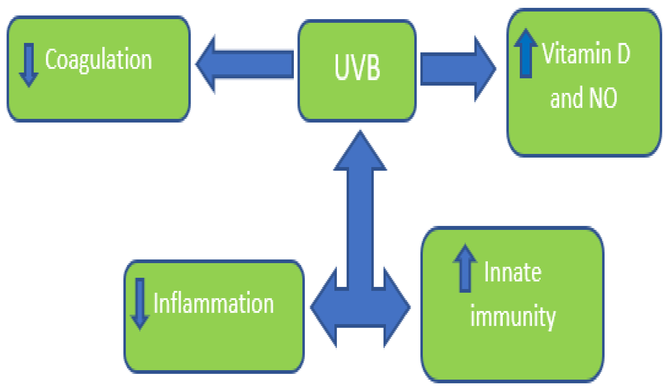
We hypothesize that improving immunoregulation with UVB phototherapy will reduce disproportionate inflammation during the infection, as well as hypercoagulation that are hallmarks of severe COVID infections[8,9]. To test our hypothesis, we are conducting a placebo-controlled, double-blinded, randomized clinical trial of narrow-band UVB (NB-UVB) light in hospitalized Covid-1.4 patients.

## Methods

- Pilot phase enrolled 30 patients at a single site and will be followed by an adaptive design up to 300 patients at 10 sites.
- Inclusion criteria included age over 50, a positive PCR Covid-19 testing, at least one comorbidity and oxygen saturation below 94.
- Exclusion criteria included required ventilatory support at time of enrollment, light sensitive medications and in-patient vitamin D supplementations.
- Other data such as BMI and blood pressure are also measured.
- The phototherapy is used as an adjunct treatment.
- A visually identical light that emits no UVB is used as placebo.
- A minimum of 25% body surface area is exposed to the UVB light.
- Patients were treated for 8 days and followed-up for 20 days.
- Blood draws are performed on day 1 pre-treatment and on days 3, 5 and 8 post-treatment

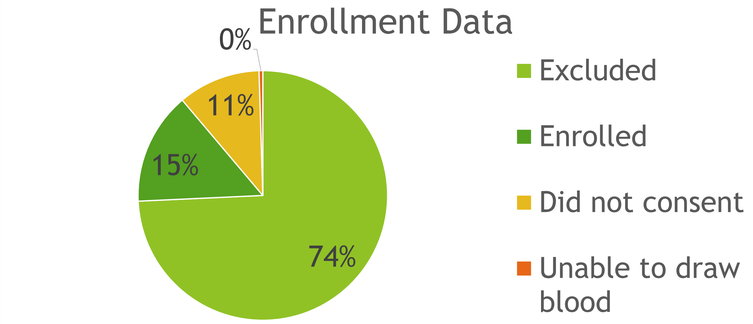
## Endpoints

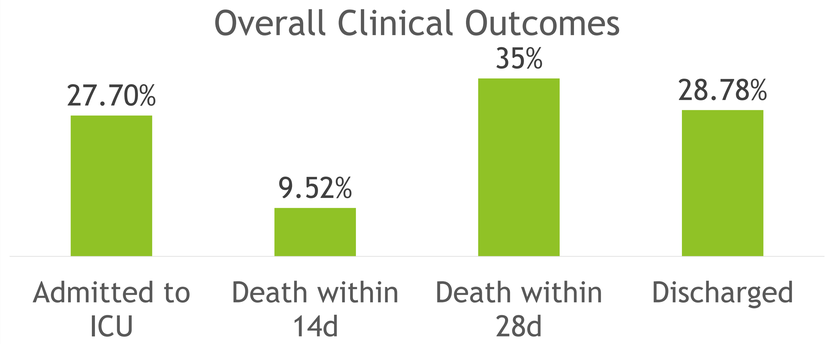
- Primary objective is to demonstrate safety and efficacy by showing improved clinical outcomes.
- Secondary objectives are to demonstrate a decrease in Th1 levels, with an increase in Th2 and Treg T-cells. D-dimer and partial thromboplastin time (PTT) are also measured. Lastly, vitamin D levels are measured to demonstrate the efficacy of NB-UVB in this regard.


## Baseline Results

- Between May 24, 2021, and August 19, 2021
- Mean hospital stay: 12.9 +/- 8.96 days
- Mean age of 67.3 years (range 50-92)
- Mean body mass index of 32.4 kg/m2 (22.9-61.0)
- Mean treatments received 3.8 (1-8)




## Conclusions

Enrollment for the pilot phase is completed. Data are currently embargoed and are being analyzed. We anticipate reporting the results of this trial in the next month.

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