Assessing the safety and efficacy of multi-dosed topical Rose Bengal Sodium in a murine model of full-thickness cutaneous injury

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**BACKGROUND**

Wound healing, particularly in full-thickness injuries, presents a significant clinical challenge. Traditional approaches often yield limited success, highlighting the need for innovative treatments. We have reported that Rose Bengal photodynamic therapy accelerates wound closure and improves wound healing. This study seeks to assess the therapeutic potential of PV-10, a recent iteration of Rose Bengal by Provectus Biopharmaceuticals, in enhancing wound healing processes. Since photoactivation may not be available in every clinical setting, we sought to compare the efficacy and safety of single-dose versus multidose PV-10 application under monochromatic green light (MGL) and ambient light, respectively.

**DESIGN & METHODS**

**Deep Cutaneous Injury**
- Balb/c 7-week-old (N=52)
- Cutaneous full-thickness injury: 6-mm diameter punch biopsy
- RBS = 0.01% (in 0.9% saline) PV-10 (PVCT Biopharmaceutical Inc.) every other day. All treatments in 20% (w/vol) PF-127 hydrogel
- Ambient light conditions or MGL = monochromatic green light (λ=532 nm) @ 2.5cm; 235mW/cm²; 1500 sec; dose = 35J/cm² (for clinical applicability)

**Outcome Measures and Observations**

**Primary outcomes**
- Full CBC and comprehensive blood chemistry panel
- Body weight, food consumption, organ appearance

**Secondary outcomes**
- Wound Closure
- Epidermal water loss, erythema
- Wound histology
- Vascularization

**RESULTS**

PV-10 does not affect body weight

**Comprehensive Blood Chemistry**

Liver & Pancreas Function

Glucose & Electrolytes

Kidney Function

**Comprehensive Blood Chemistries**

**Liver & Pancreas Function**

**CONCLUSION**

- Multidose (MD) application of 0.01% RBS every other day to full-thickness wounds showed
  - No toxicity or mortality
  - No loss in body weight
  - No organ abnormalities
  - No observed-adverse-effect level at the highest tested dose
  - Transdermal Water Loss is significantly reduced by 14 days supporting improved skin barrier function
  - Erythema is increased at 7 days with both treatment regimens suggesting increased blood flow and granulation tissue formation required for wound healing
  - Accelerated wound closure with MD RBS 0.01% (significant difference at 3 days)
  - MD RBS 0.01% increases collagen density at 7 and 14 days supporting increased wound remodeling and tissue regeneration
  - Vascularization is increased in the MD RBS 0.01% group between 3 and 14 days supporting pro-angiogenic activity needed for wound closure
  - MD RBS 0.01% reduces angiogenesis after wound closure (day 14) which is beneficial in preventing fibrosis

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