

Topical Sodium Nitrate Ointment for Sickle Cell Disease

Summary (1024-character limit)

The National Institutes of Health, through The National Institutes of Health - Clinical Center (NIH-CC) and the National Heart Lung and Blood Institute (NHLBI), seeks licensing and/or co-development partners for a nitric oxide cream for the treatment of ulcers associated with sickle cell disease.

NIH Reference Number

E-149-2014

Product Type

- Therapeutics

Keywords

- Sickle Cell Disease, SCD, Blood Disorder, Topical, Cream, Ointment, Sodium Nitrate, Nitric Oxide, Wound Healing, Topical Therapeutic, Vascular Ulcers, Haksong

Collaboration Opportunity

This invention is available for licensing.

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Description of Technology

Chronic leg ulcers are a debilitating vasculopathic complication for some patients with sickle cell disease (SCD). Prevalence of leg ulcers varies based on age and geographic location; about 5-10% of all SCD patients may suffer leg ulcers. These leg ulcers are painful, result in infections, hospitalization, disability, and negatively impact the patient's social and psychological wellbeing on an ongoing basis. Until recently, patients with SCD only had one drug treatment option: hydroxyurea, which was approved by the Food and Drug Administration (FDA) in 1998 in adults and in 2017, in children age 2 and older.

However, there are no FDA-approved treatments specifically to treat SCD ulcers. The ulcer may take months or even years to heal. Opioid drugs are often administered to relieve intense pain symptoms, but the opioids do not treat the underlying wound conditions and carry addiction risks with chronic use.

Thus, there is an unmet medical need to develop therapies that heal SCD ulcers.

Scientists at the National Institutes of Health (NIH) have developed a novel medical formulation; a

promising sodium-nitrite cream for treating leg ulcers in SCD patients. The topical ointment helps increase nitric oxide levels in the wound. The specific formulation allows nitric oxide gas to dilate vessels by relaxing their smooth muscle cells. This aids healing the wound by increasing the amount of oxygenated blood that reaches the ulcer. A completed Phase 1 clinical trial of this sodium-nitrite cream has demonstrated that the therapy is safe, well-tolerated, and significantly reduces ulcer size and pain in the patients enrolled. This promising treatment has now received funding from a U.S. FDA-awarded grant through the Orphan Products Clinical Trials Grant Program to fund Phase 2 clinical studies for this treatment.

Potential Commercial Applications

- Cream/ointment for the treatment of ulcers related to sickle cell anemia
- Treatment for localized deficiency in nitric oxide

Competitive Advantages

- Completed Phase 1 studies
- Funded for Phase II studies - through the FDA Orphan Products Clinical Trials Grant Program
- Possible Orphan Drug Designation

Inventor(s)

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Development Stage

- Clinical

Publications

Minniti C, et al. Topical sodium nitrite for chronic leg ulcers in patients with sickle cell anaemia: a phase 1 dose-finding safety and tolerability trial. [[PMID 25938131](#)]

Patent Status

- **U.S. Patent Filed:** U.S. Patent Application Number 15/525,557 , Filed 09 May 2017
- **U.S. Patent Filed:** U.S. Patent Application Number PCT/US2015/060015 , Filed 10 Nov 2015
- **Foreign Filed:** - Patent Application 15798623.3 , Filed 10 Nov 2015

Therapeutic Area

- Hormonal Systems, Endocrine, and Metabolic Diseases
- Cardiovascular Systems
- Musculoskeletal