Hyperspectral Tissue Oxygenation Monitoring of Biomarkers to Assess the Role of Erythropoietin in Improving the Healing of Diabetic Foot Ulcers

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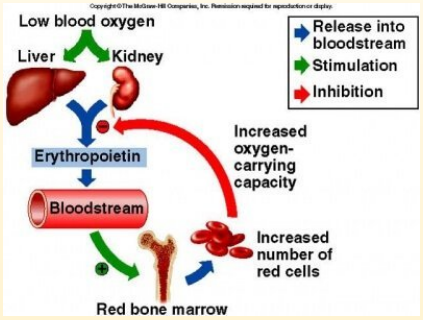
♦ Background

At least 70,000 lower extremity amputations are performed annually in the US in patients with diabetes, procedures which are often necessary due to complications of poor vascular supply. Surgical attempts to restore vascular supply and enhance delivery of blood to lower extremities have poor long term success owing to established macro and micro-vascular insufficiency. Therefore, it is important to identify ways to prevent these amputations from occurring in the first place.

Surgical attempts to restore vascular supply and enhance delivery of blood to the leg have met with poor long term success because of established macro- and micro-vascular insufficiencies.

Alternatively, boosting red blood cell production and angiogenesis through the use of erythropoietic (EPO) agent could provide an additional avenue for increasing oxygen delivery to the lower extremity. Erythropoietin is a glycoprotein growth factor produced in the kidneys that regulates the proliferation and differentiation of erythroid precursor cells, thereby increasing hemoglobin levels. Studies have shown an interaction between EPO, vascular endothelial growth factor, and endothelial cell mitosis and motility both leading to enhanced angiogenesis, which is beneficial for wound healing.



♦ Study Aims

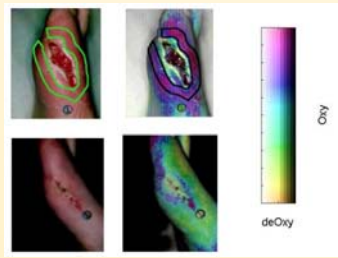
Erythropoietin (EPO) is a hormone naturally produced by the kidneys in response to low blood oxygen that induces bone marrow to produce red blood cells. This study purports to test whether administration of EPO improves oxygen delivery to tissues of patients with diabetic foot ulcers sufficient to promote wound healing. In addition, we will explore whether a non-invasive camera based system (Medical Hyperspectral Imaging) is viable for monitoring the delivery and extraction of oxygen in wounded tissue.

♦ Methods: Phase 1

Demonstrate that EPO improves oxygen delivery to the lower extremity MHSI imaging. Measurements will be made in a pilot study on 10 patients with anemia due to chronic renal failure or are undergoing chemotherapy in whom, treatment with an EPO analogue is being initiated with dosing as clinically indicated. Measurements are made prior to treatment, then at 2 week intervals for 26 weeks. At each visit, MHSI imaging will be correlated with CBC. In addition, Full laboratory and physiologic measurements including electrolyte and renal and hepatic function panels will be collected at the beginning and end of the study.

♦ Methods: Phase 2

Demonstrate that EPO administration can have a beneficial effect on diabetic foot ulcers. 40 subjects with diabetic foot ulcers and anemia will be recruited. Subjects will be divided into two cohorts; one half will be placed in Group A: receiving EPO therapy and one half into Group B: not receiving EPO therapy. Both will be monitored prior to dosing, then at 2 week intervals for 26 weeks. Monitoring will include serial wound evaluations, complete blood counts, additional laboratory work and MHSI measurements of several sites including the wounded tissue.



♦ Expected Results

It is expected that hemoglobin and hematocrit levels will increase with erythropoietin use. Increased hemoglobin and hematocrit levels will increase oxygen delivery to damaged tissue and promote wound healing. Interaction between EPO and VEGF promotes angiogenesis, which should further accelerate wound healing in diabetic ulcerations.

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