

Hyperbaric Oxygen Therapy in Diabetic Wound Healing

Study Title:

Hyperbaric Oxygen Therapy as a primary treatment for Wagner Stage II diabetic foot lesions – A randomized and controlled clinical trial.

Study Type:

Multi-Center randomized, double-blind placebo controlled clinical trial.

Study Intervention & Protocol:

Tissue oximetry screening followed by 30 once daily hyperbaric treatments, to commence following at least 30 days from diagnosis and no documented improvement with standard care. After enrollment and tissue oximetry testing, randomization sequence will be provided via an internet accessible database.

Active: 2.0 ATA for 90 minutes, Q.D, five days weekly for 30 treatments.

Control: 1.0 ATA, Q.D, five days weekly for 30 ‘treatments’.

Study Population:

Adult diabetic patients suffering from Wagner Stage II lower extremity ulcers that are complicated by local and reversible tissue hypoxia, unresponsive to standard care.

Study Enrollment:

Number to be determined by analysis of the relative existing literature, and conducted in conjunction with the University of South Carolina’s Biostatistical Department.

Facility Recruitment:

Selected participating “HORTIS” centers, VA medical centers, and other interested institutions.

Outcome Measures:

Difference between groups in rate of healing; time to healing; wound debridement; amputations; quality of life; economics and complications. Analysis of outcome measures will be carried out using Statistical Analysis Software (SAS).

Sponsoring Organization:

The Baromedical Research Foundation, Columbia, South Carolina, USA
(www.baromedicalresearch.org)

The Baromedical Research Foundation will underwrite study infrastructure costs. Additional funding sources to be identified.