Study Protocol

Official Title:
The Effects of Hyperbaric Oxygen Therapy at Intermediate Pressure (1.75 ATA) on VO■ Max and Inflammatory Cytokine Profiles

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1. Background and Rationale

Hyperbaric oxygen therapy (HBOT) involves breathing 100% oxygen at pressures greater than atmospheric pressure. Prior research suggests HBOT may improve cardiovascular fitness and modulate inflammatory processes. While higher pressures such as 2.0 ATA have demonstrated physiologic benefits, they may be associated with increased risk and cost. Lower pressures may provide fewer benefits. Intermediate pressures, such as 1.75 ATA, remain underexplored. This study aims to evaluate whether HBOT at 1.75 ATA improves aerobic capacity and inflammatory biomarkers while maintaining an acceptable safety profile.

2. Study Objectives

Primary Objective: To assess changes in VO■ max following HBOT at 1.75 ATA.

Secondary Objective: To evaluate changes in circulating inflammatory cytokine profiles following HBOT at 1.75 ATA.

3. Study Design

This is a prospective, single-arm, pre–post interventional study. Participants will undergo baseline assessments, receive HBOT intervention, and complete follow-up assessments at prespecified time points.

4. Study Population

The study will enroll physically active adults aged 30 to 60 years. Participants must be generally healthy and capable of completing maximal exercise testing. Individuals with medical contraindications to HBOT or exercise testing will be excluded.

5. Intervention

Participants will undergo 24 hyperbaric oxygen therapy sessions over approximately eight weeks. Each session consists of exposure to 100% oxygen at 1.75 ATA for 100 minutes, including scheduled air breaks. All sessions will be conducted in a supervised clinical hyperbaric facility.

6. Outcome Measures

Primary Outcome: Change in VO■ max measured via cardiopulmonary exercise testing.

Secondary Outcomes: Changes in circulating inflammatory cytokines measured from venous blood samples.

7. Study Procedures and Timeline

Assessments will occur at baseline, mid-intervention, immediately post-intervention, and approximately four weeks after completion of HBOT. Assessments include VO■ max testing, blood sample collection, and vital sign monitoring.

8. Statistical Analysis Overview

Within-participant changes will be analyzed using paired statistical methods. Continuous outcomes will be summarized using descriptive statistics. Statistical significance will be assessed using appropriate parametric or nonparametric tests based on data distribution.

9. Safety Monitoring and Ethics

Participants will be screened for contraindications prior to enrollment and monitored throughout the study. Adverse events will be documented and reviewed by the study team. The study has received approval from an Institutional Review Board, and all participants will provide written informed consent prior to participation.