

PROTOCOL: Neuroimaging During Pure Oxygen Breathing

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NCT number: NCT03268590

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Consented study participants will be asked to come to the Case Western Reserve University Magnetic Resonance (MR) Facility located within University Hospitals on 11100 Euclid Ave, Cleveland OH 44106 at a scheduled date/time. Data collection will involve 1 visit lasting approximately 3-4 hours in length.

### PROCEDURE:

1. Confirmation of signed informed consent & repeat MRI screening to ensure subject safety
2. Obtain focused neurological history and physical examination
3. Obtain baseline vital signs
4. Apply HD-EEG head cap on scalp, apply EEG gel, and program EEG acquisition software, check impedances
5. Obtain 5 minutes of baseline EEG recording
6. While the participant is breathing room air and EEG is being recorded, administer baseline neurocognitive assessments
7. Obtain baseline arterial blood sample for blood gas and venous blood sample for inflammatory markers. Perform Allen test for collateral circulation prior to obtaining arterial blood sample. Apply pressure over the artery for 5-10 minutes after the blood sample is obtained to minimize bleeding
8. Obtain baseline exhaled breath sample
9. Transfer participant to MRI scanning room. Final MRI safety check
10. Apply MRI-compatible respiratory monitoring sensors, pulse oximeter probe, nasal cannula, face mask
11. While the participant is breathing room air, MRI scan and simultaneous EEG recording begins
12. Continuously monitor heart and respiratory rate, oxygenation during scanning session
13. After baseline MR scans are acquired, scanning and EEG recording continues and oxygen administration is begun
14. Following 30 minutes of 100% oxygen administration, MRI scan ends. Arterial blood gas sample and exhaled breath sample are obtained while oxygen administration and EEG recording continues. Perform Allen test for collateral circulation prior to obtaining arterial blood sample. Apply pressure over the artery for 5-10 minutes after the blood sample is obtained to minimize bleeding
15. While continuing 100% oxygen breathing and EEG recording, repeat neurocognitive assessments
16. 100% oxygen breathing discontinued. Room air breathing begins
17. The participant is observed and vital signs are assessed for 30 minutes during room air breathing. Arterial puncture site is assessed for hemostasis. Participant is assisted to remove EEG gel
18. Participant is contacted within 1 week to assess for development of any adverse events

#### STATISTICAL ANALYSIS PLAN:

General statistical approaches: Sample size estimation and power analyses were based on a minimum statistical power of  $\geq 0.80$  at a two-tailed significance of 0.05. Physiologic measures were continuous in nature and frequency analyses with normality plots providing information of data distributions.

Descriptive statistics include the mean, standard error of the mean (SEM), and range. Independent samples t-tests were utilized to compare males and females, incorporating the Levene test for homogeneity of variance. Paired t-tests were used to compare physiologic measures in 21% FiO<sub>2</sub> versus 100% FiO<sub>2</sub>.