

Do you have a diagnosis of **Complex Regional Pain Syndrome?**

If so, you might be eligible for a research study that aims to decrease and/or resolve the pain derived from this condition.

The purpose of this research study is to determine if Nitrous oxide is an effective treatment for Complex Regional Pain Syndrome. Nitrous oxide also known as “laughing gas,” is commonly used throughout the world as a safe, low potency inhaled anesthetic gas. The treatment consist in three (3) breathing sessions (2 hours each) over the course of one week. .

Participants will be provided with \$50 for each breathing treatment session (\$150 total).

This study is being conducted at Cleveland Clinic main campus (Cleveland, Ohio);

For more information, please call or email:

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Study Intervention: Study subjects will be randomly assigned (like a flip of a coin) to the treatment group (breathing 50% nitrous oxide) or the control group (breathing 50% oxygen). Because nitrous oxide is sedating, patients in both groups will receive a mild sedative to mimic the effects of nitrous oxide. The purpose of this step is to prevent patients from determining which study group they were assigned to, which is necessary for proper interpretation of the study results. The three (3) breathing treatment sessions will take place over the course of one week with 2 or 3 days between each session. Both groups will undergo inhalation therapy for a duration of 2 hours via an FDA-approved mask breathing circuit. Vital signs (blood pressure, respiratory rate, heart rate) will be monitored every 30 minutes. Pulse oximetry monitoring will be continuous. Patients will be monitored for side effects including nausea, vomiting, desaturation, sedation, respiratory depression, and dizziness.

Study Protocol: If you decide to participate in the study, you may be asked to send your clinical records in order to verify if you are eligible. If so, you will be asked to come to Cleveland Clinic main campus. Please remind you will need a driver. You will also be asked to refrain from eating any food during the eight hours prior to the treatment sessions. For the first scheduled treatment session you will fill out baseline questionnaires about the characteristics of your pain as well as your daily opioid (pain relief) medication used during the previous week. You will receive a phone call 1 week before the first session to remind you to start filling out the opioid use log. The treatment consist in three (3) breathing sessions (2 hours per session) over the course of one week. Patients will not know the treatment group they were assigned to. Assigned research investigators administering the treatments will not be blinded. At the conclusion of inhalation therapy, the gas will be turned off and patients will breathe room air. All patients will be monitored for an additional 30 minutes. This recovery time is more than sufficient to ensure nitrous oxide is completely eliminated in those patients who receive it. Patients will be monitored and asked about side effects. After the conclusion of the third treatment session, patients will be followed with phone questionnaires 1 week and 1 month after.