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Now Enrolling

Open Label Optimization (OLO) Clinical Trial

Evaluating the SAINT™ Neuromodulation System for the Treatment of Major Depressive Disorder

The prospective, multi-site Open Label Optimization (OLO) clinical trial is now enrolling up to 1,000 adults throughout the U.S. experiencing a major depressive episode who have failed to receive satisfactory improvement from a prior antidepressant medication. The OLO study is designed to further evaluate the effectiveness of the SAINT™ Neuromodulation System for the treatment of adults with major depressive disorder (MDD) in a real-world setting.

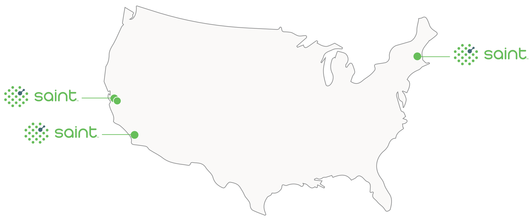
ELIGIBILITY

A complete list of eligibility and exclusion criteria will be explained to you by the study doctor.

You must be 18 years or older and have failed to receive satisfactory improvement from prior antidepressant medication in the current episode.

You have a confirmed primary clinical diagnosis of MDD.
You are able to have a brain MRI scan.
You are not pregnant.

To see if you or a loved one qualifies for this SAINT™ Neuromodulation System clinical trial, contact the site on the map below closest to you.



THE SAINT™ NEUROMODULATION SYSTEM

The SAINT™ Neuromodulation System is a novel treatment for depression. SAINT™ uses non-invasive magnetic stimulation with personalized targeting to specific areas of the brain associated with depression. The treatment is investigational and delivers accelerated, personalized targeted stimulation to regions in the brain to treat MDD.

SAINT™ Therapy is delivered on an accelerated timeline—10 sessions a day, composed of 10-minute treatments with 50-minute breaks for five consecutive days.

PARTICIPATION DETAILS

DURATION

Each patient will participate in follow-up for 1 year. This will include the treatment and follow-up calls.

COST

There is a cost to participate in the OLO clinical trial.

For more information, please contact the study site. Additional clinical trial information may be found at clinicaltrials.gov.

For clinical study sites, additional OLO study information may be found here.

Scientific Evidence

Peer-Reviewed Articles

In completed clinical trials, delivery of SAINT™ therapy for MDD has resulted in a significant reduction in depressive symptoms following the five-day treatment protocol.

Stanford Neuromodulation Therapy (SNT): A Double-Blind Randomized Controlled Trial

American Journal of Psychiatry | Volume 179, Issue 2 | February 2022

Summary: Depression is the leading cause of disability worldwide, and half of patients with depression have treatment-resistant depression. This clinical study tested the safety and effectiveness of personalized neurostimulation with a novel protocol for Major Depressive Disorder (MDD). The study was designed to address the limitations of the current intermittent theta-burst stimulation (iTBS). Results from the double-blinded randomized controlled trial (RCT) evaluating SAINT demonstrate that this novel approach has the promise to be a reproducible, rapid and effective treatment for severe, intractable depression. Fourteen people received active treatment, and another 15 people received sham (placebo) treatment. The results indicate that 79% of people in the active treatment arm entered remission—compared to people in the sham or control treatment arm, where 13% of the people entered remission from depression.

View Authors

Stanford Accelerated Intelligent Neuromodulation Therapy for Treatment-Resistant Depression

American Journal of Psychiatry | Volume 177, Issue 8 | August 2020

Summary: New antidepressant treatments are needed that are effective, rapid-acting, safe and tolerable. The study examined the feasibility, tolerability and preliminary effectiveness of SAINT neuromodulation treatment for treatment-resistant depression. Twenty-two participants with treatment-resistant depression received open-label SAINT treatment. One participant withdrew, leaving a sample size of 21. Nineteen of 21 participants (90.5%) entered remission based on the Montgomery-Åsberg Depression Rating Scale (MADRS). Neuropsychological testing demonstrated no negative cognitive side effects.

View Authors

In these studies SAINT™ has been shown to be effective in the treatment of MDD, with approximately 80-90% of patients achieving remission of depression symptoms following the five-day treatment protocol. Treatment with SAINT™ is safe and well-tolerated according to results, indicating that this new treatment promises to be a rapid and effective treatment for treatment-resistant major depression.

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Open Label Optimization (OLO) Awareness Toolkit

A comprehensive set of template materials and assets to help you recruit potential participants and inform referring medical professionals about the Open Label Optimization (OLO) study. The OLO study is designed to assess the effectiveness of the SAINT™ Neuromodulation System to treat Major Depressive Disorder (MDD).

LOGIN

PASSWORD

Submit

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Getting Started

This toolkit is designed to help your site connect to potential participants and other clinicians in your communities regarding the Open Label Optimization (OLO) clinical trial with the SAINT™ Neuromodulation System. The patient recruitment materials included in this toolkit are approved by Magnus Medical and Advarra, the central IRB. If you have a local IRB, you are responsible for obtaining approval prior to use. You can use the provided approved language and imagery in different combinations to tailor to your patient demographic. You cannot make any changes to verbiage or content without consulting and obtaining written approval from Magnus. Keep in mind that any changes must be approved by the IRB prior to use.

Easily download all the resources and tools available.

Patient Facing

Recruitment and Informational Materials

- Patient study information
- Social media guide and toolkit
- Webpage language
- Digital and print ads
- Radio PSA
- OLO imagery

Community Engagement

Community Facing Informational Materials

- Referring physicians
- Open house guide
- Open house invitation
- Newsletter & blog

Public Relations

Promotional and General Awareness Materials

- Media outreach guide
- Press release
- Media pitch letter
- Backgrounder & fact sheet
- Logos

We're here for you.

For OLO physicians and OLO staff, please contact:

Jessica Hawkins
clinicaltrials@magnusmed.com
650 525-4485

For questions about the OLO Awareness toolkit or to request printed materials, please email us at clinicaltrials@magnusmed.com.

Contact Us