

## Background

The purpose of this study is to investigate how well low dose naltrexone (LDN) works for neuropathic pain in patients with HIV.

- People diagnosed with HIV/AIDS are living longer and experiencing more chronic conditions, including chronic pain. This pain is often treated with opioids, which is not advisable per national guidelines.
- Naltrexone (*standard dose: 50 mg daily*) is FDA approved for the treatment of addiction.
- LDN (*low dose: 1-5 mg daily*) has been shown to be effective for the treatment of chronic pain, including neuropathic pain.
- HIV/AIDS is associated with an increase in cytokines (a group of proteins made by the immune system that act as chemical messengers). LDN is associated with a decrease in cytokines. **We will also study the effect of LDN on cytokines.**

## Research Team

### Principal Investigator

Anne Marie McKenzie-Brown, MD  
amckenz@emory.edu

### Co-Investigators

Vinita Singh, MD

Kimberly Workowski, MD

Igho Ofotokun, MD

Brian Bobzien, MD

### Clinical Research Nurses:

Kathy Egan, BSN, RN

Akanima Okpokowuruk, BSN, RN

Gretchen Windsor, BSN, RN

Anesthesiology Research Line:  
404-251-0759

[anesresearch@emoryhealthcare.org](mailto:anesresearch@emoryhealthcare.org)

ClinicalTrials.gov ID: NCT05537935

**LDN is investigational and not FDA-approved for this indication.**

## Study Visit Summary

- Participation lasts **~13 weeks** and consists of **14** total visits (includes telephone and in-person visits).
- The telephone calls will be brief, up to about 15 minutes. The in-person visits may last approximately 1 hr.
- In-person visits occur at weeks **1, 4, 8** and **12** & primarily occur at the EUH clinic on Emory's main campus or EUHM on Peachtree
- A blood sample will be obtained at the initial and final visits.
- You will be provided a 4-week supply of study medication at visits 1, 4, and 8.
- You will be compensated up to \$100 for your participation.

*You may also choose to participate in the control group instead (no study drug treatment) – 12 weeks, **online and telephone visits only**, no blood sampling, compensated up to \$25 at the end.*



## Who Can Participate?

### You must:

- Be 18-75 years old
- Be diagnosed with HIV
- Have an average pain score of >4/10

### You must NOT:

- Be currently taking opioids
- Be pregnant or nursing
- Have severe liver disease
- Be on dialysis
- Active drug or alcohol use disorder (marijuana use is not disqualifying)

If you are interested in participating or would like more information, please contact:

**Anesthesiology Research  
Line:  
404-251-0759**

Visit our website to learn more:



ClinicalTrials.gov ID: NCT05537935

## Low Dose Naltrexone (LDN) for Treatment of Neuropathic Pain in HIV Patients:

A Prospective, Pragmatic, Open-Label Clinical Trial



**EMORY**  
UNIVERSITY  
SCHOOL OF  
MEDICINE

---

DEPARTMENT  
OF ANESTHESIOLOGY