Stanford MEDICINE
School of Medicine

UCSF
University of California San Francisco

Volunteers needed: Help revolutionize understanding and treatment of ALS

Clinical trials are research studies that look to find better ways to prevent, diagnose, or treat disease.

OP-801-001: ALS Imaging study

Protocol OP-801-001: A Phase 1/2 Study to Evaluate the Safety, Pharmacokinetics and Biodistribution of an Imaging agent, ^{18}F-OP-801 (^{18}F Hydroxyl Dendrimer), After Intravenous Administration to Patients with Amyotrophic Lateral Sclerosis (ALS) and Healthy Volunteers (HV)

OP-801-001 is a clinical study to evaluate an imaging agent (^{18}F-OP-801) in healthy volunteers (HVs) and patients with ALS.

About the Imaging Agent (^{18}F-OP-801)

^{18}F-OP-801 may allow the mapping and characterization of neuroinflammation caused by ALS, which will in turn help to develop future treatments for this devastating disease.

The purpose of this study is to evaluate the safety and tolerability of ^{18}F-OP-801.

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Who can participate?

Patients who have been diagnosed with Amyotrophic Lateral Sclerosis (ALS) are invited to participate in this study.

Participation in this study is voluntary. You are free to choose to participate or not participate. If you choose to participate, you may leave the study at any time. If you decide not to participate, your doctor can discuss other treatment options if needed.

Volunteers will be compensated up to $1500 for their participation. Additional travel funds may be available if needed.

For complaints, concerns, or participant's rights, contact 1-866-680-2906.

The following criteria must be met to qualify for the study:

- Confirmed ALS diagnosis
- Between 18 and 80 years old
- Body weight less than 120 kg or 264 lbs
- Able to pass a drug test at the screening visit
- Able to lay flat with no movement for up to 90 minutes
- No kidney or liver function impairment
- No metallic implants unsafe for MRI
- Not receiving any other investigational medicines

**Additional criteria will be assessed at the screening visit*

What do I have to do if I participate?

Total study participation requires 3 or 4 visits to Stanford University in Palo Alto within a maximum of 89 days. There will be 1 screening visit to determine eligibility up to 60 days before the dosing day. If eligible, ALS participants will return for 1 or 2 full-day visits and 1 brief follow up visit 15 days after receiving 1-2 doses of ^{18}F-OP-801. Visits will include:

- PET/CT or PET/MRI and MRI imaging
- Blood draws
- Urine collection

If you are interested in helping revolutionize imaging for neuroinflammatory diseases, please contact Maria Jovin:

Call (650) 724-0156
Or email mjovin@stanford.edu