

MSK-DA01 Parkinson's Disease Clinical Trial

University of California, Irvine | UCLA-UCI Alpha Stem Cell Clinic at UC Irvine

Study Title: Phase 1 Study to Assess the Safety and Tolerability of Human Embryonic Stem Cell-Derived Midbrain Dopamine Neuron Cell Therapy (MSK-DA01) For Advanced Parkinson's Disease (STEM Parkinsons)

Lead Investigator: Claire Henchcliffe, MD, DPhil

Sponsor: BlueRock Therapeutics, Inc

What is the study?

The purpose of this research study is to see whether an injection of MSK-DA01 is a safe and tolerable study intervention for Parkinson's disease (PD), and whether the signs and symptoms of PD change in response to this study intervention. The study will also see how participants feel about their quality of life after the transplant. This study is the first time that MSK-DA01 is being tested in people.

How long will my participation last?

Participants will be in this study for about 2 years and will have up to 28 study visits. The one-time surgical procedure will occur at Memorial Sloan Kettering in New York, and pre-operative imaging performed at Northwell Health in New York.

How can I take part in this trial?

Please note this may not be a complete list of eligibility criteria.

Main Inclusion Criteria

- Are between the ages of 60 to 76 years old
- Have been diagnosed with PD between 5 and 15 years ago
- Are able to participate in all study visits and evaluations, including brain MRI

Main Exclusion Requirements

Participants cannot participate in this study if:

- Have PD with only tremor-based symptoms
- Have a history of Deep Brain Stimulation, lesion therapy, or gene therapy for PD

- Had prior surgical or radiation therapy to the brain or spinal cord
- Are pregnant or breastfeeding

How does it work?

In this study, 2 different doses of MSK-DA01 will be given to several study participants. The first 5 participants will receive the lower dose, and the next 5 will receive the higher dose. Your study doctor will tell you which dose you will receive. This study will use investigational devices to deliver the MSK-DA01 cells into your brain during surgery. The stem cells administered cannot be removed once they are implanted in your body. You will receive immunosuppressant medications for 1 year.

Where is the study conducted?

The main study will occur at the University of California, Irvine (UCI) in CA. The surgical site for the study is located at Memorial Sloan Kettering Cancer Center (MSK) in NY, and the imaging site is located at Northwell Health, Feinstein Center for Neurosciences in NY.

Will I be compensated?

Participants will not receive any payment for their participation in this study.

For more information please contact:

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