

PBR28 Brain Imaging

This study is being conducted to learn more about inflammation in the brain of people with ALS and PLS. Our study will examine whether particular cells called microglia are hyperactive in the nervous system of people with ALS or PLS using Magnetic Resonance Imaging (MRI) and Positron Emission Tomography (PET). This information could help improve the diagnosis and development of treatments for other patients with ALS or PLS in the future.

Study participation involves up to six hospital visits over the course of 24 months, plus brief phone calls every three months for up to 48 months after enrollment. Procedures include a combined MRI/PET scan, clinical measures such as breathing tests, and questionnaires. Participants will be reimbursed for parking and receive compensation of \$150 for completing the baseline MRI/PET scan. Participants may elect to complete four additional scans, compensated at \$150 each, during their follow up visits at the hospital.

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MASSACHUSETTS
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Imaging Biomarker Studies
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For more information about any of these trials,
please contact the listed study coordinator or
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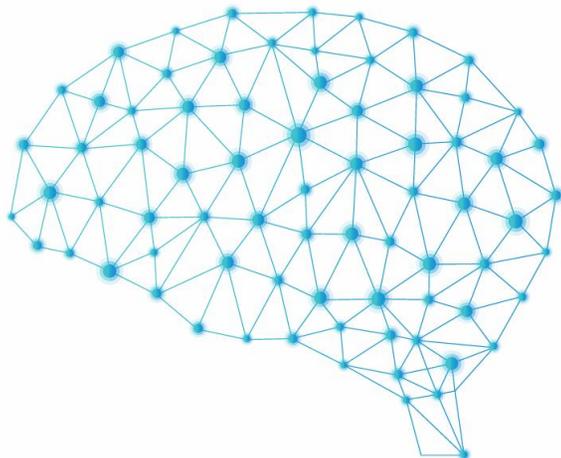
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For more information visit

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<http://www.alsconsortium.org>



Spine-ALS

We are doing this research to learn more about changes in the spinal cord and brain in ALS. “Microglia” are a type of immune cell that we are particularly interested in. We would like to find out if microglia are activated in the spinal cord and brain of individuals with ALS. Special imaging techniques are now available to test for changes in microglia. Magnetic Resonance Imaging (MRI) and Positron Emission Tomography (PET) are two tests that allow us to take pictures and “look inside” the body without surgery. MR-PET scanners use both MRI and PET tests at the same time. The MR-PET scanner may give clearer images and more information about the inside of the body.

If you choose to take part in this study you may have 2 visits at MGH, up to 3 months apart. We will pay you \$150 for completion of the spinal cord MR-PET scan. If you choose to participate in the optional brain MR-PET scan you will be paid an additional \$50 for completion.

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TRACK-ALS

+Healthy Volunteers

TRACK-ALS is a multicenter, longitudinal study which aims to identify imaging and biofluid biomarkers in people with ALS to expand the understanding of disease pathology and progression. By identifying changes that occur in the blood, brain, and cerebrospinal fluid (CSF) of individuals with ALS, this pilot project has the potential to inform both diagnostic measures and drug development. Participation in the study for those with ALS involves approximately six onsite visits to MGH every three months for up to 18 months. Healthy volunteers are asked to make up to two onsite visits to MGH over the course of approximately two months. At these visits, participants will undergo an MRI scan to enable researchers to look at structural changes in the brain. Participants will also undergo a skin biopsy and have blood drawn for analysis of inflammatory markers and generation of stem cells for further research. Other outcome assessments for ALS participants include breathing tests, muscle tests, and questionnaires, as well as an optional lumbar puncture to enable researchers to analyze biomarkers in the CSF. Finally, a subset of participants will undergo PET scans, which allow researchers to identify regions of inflammation in the brain.

Participants must be between the ages of 18 and 80, be medically safe to undergo an MRI scan (i.e., no metallic particles in the body), and be able to safely lie flat for at least 90 minutes. Additionally, participants cannot be taking any immunosuppressive medications or have a diaphragm pacing system and cannot have a diagnosis of Parkinson’s disease, Alzheimer’s disease, unstable psychiatric disease, cognitive impairment, or renal failure.

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Tongue MRI

The goal of this study is to better understand the workings of the vocal tract in relation to the brain function during speech, swallowing, and breathing due to diseases including, but not limited to cancer (e.g., glossectomy or radiation therapy), obstructive sleep apnea (OSA), or brain disorders, and how those diseases are affected by dental procedures, treatment, or surgery. Multimodal MRI methods allow us to take pictures of what is going on inside the tongue and brain during speech or swallowing without surgery. We would like to find out if the pictures from the MRI scans can help doctors better understand tongue related disorders and how develop better treatment, surgery, and rehabilitation strategies.

The entire study visit will take about 3 hours in all. At the study visit, you fill out questionnaires, have speech task training, and have an MRI of your tongue and brain.

If you complete this clinical study, you will receive \$100, \$15 towards a meal at MGH, and free parking at MGH.

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