SESAD

Title: Phase II Trial to Evaluate Safety and Efficacy of GM-CSF/Sargramostim in Alzheimer's Disease (SESAD)

Principal Investigator: Peter Pressman, MD

Protocol: COMIRB #19-2727

For more information about the research study, please contact:

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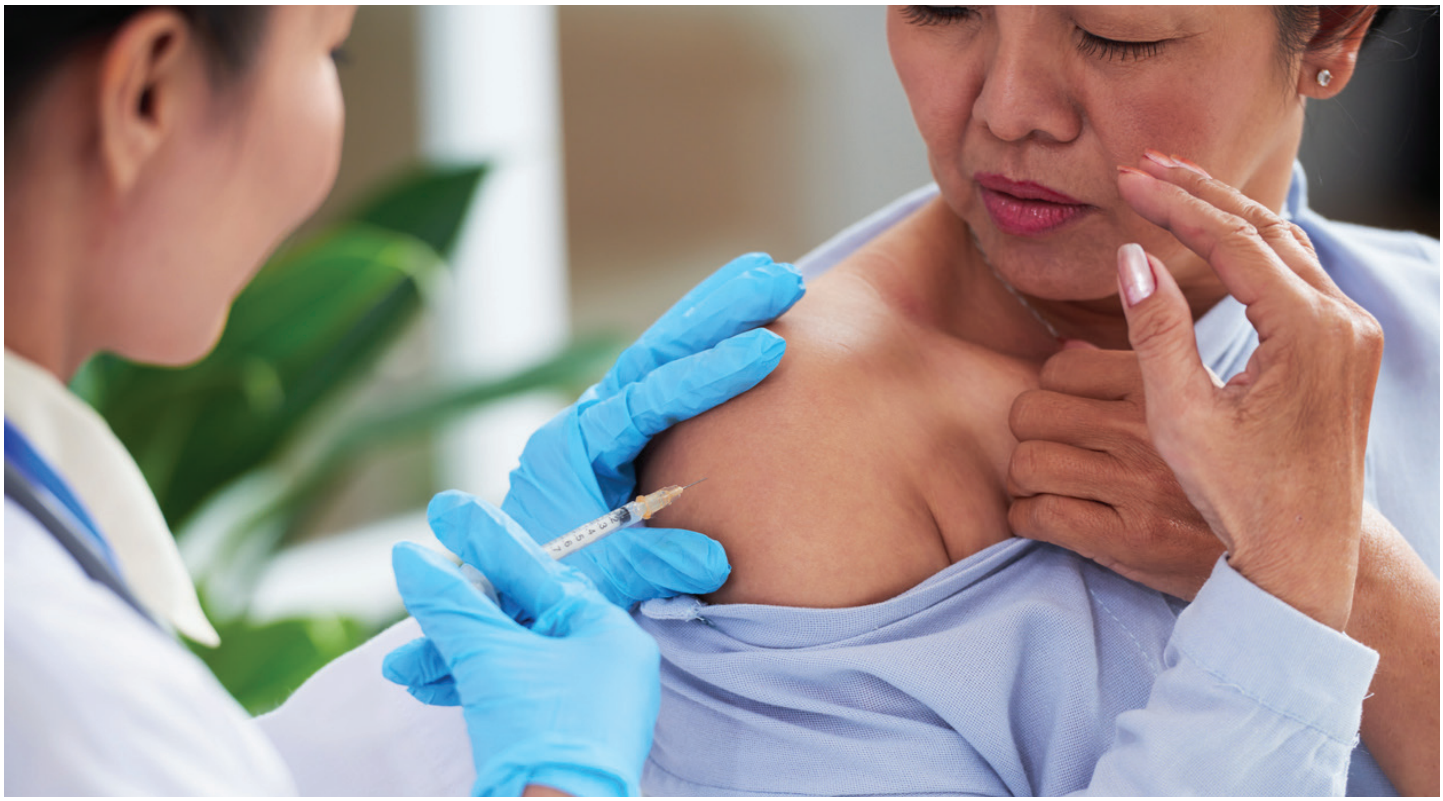
Major Goals of this Research Study

- Learn more about the safety and effectiveness of a drug called sargramostim for improving cognitive function and memory in people with Alzheimer's disease. (Sargramostim is an investigational drug, meaning it has not been approved by the FDA to treat Alzheimer's).
- Find out more about how sargramostim works within the body over a longer time period than previously studied.



Why Is this Research Important?

Alzheimer's disease is a major medical problem in the elderly, affecting 12% of those over age 65 and 40-50% of those over age 85. Current treatments offer minor benefits in slowing the development of memory problems but do not stop or reverse the damage from the disease.

This research study is important because its purpose is to determine if injections of a medicine called sargramostim in people with Alzheimer's disease is safe and effective in improving cognitive function and memory and to evaluate its safety (side effects). Sargramostim has not been FDA approved as a safe or effective treatment for people with Alzheimer's Disease.

Inclusion/Exclusion Criteria

You may be eligible for this research study if you:

- Are between the ages of 60-85
- Have a diagnosis of mild-to-moderate Alzheimer's disease (AD)
- Are willing and able to have weekly blood draws at a local LabCorp
- Are willing and able to have an MRI and PET scan
- Do not have a first degree relative diagnosed with AD before 55 years of age
- Have a study partner willing to give daily injections after training

Please note: This is a brief summary of basic screening criteria. A complete list can be found at http://bit.ly/SESAD.
Additional things may come up during the course of screening that impact enrollment eligibility, which is ultimately up to the discretion of the study team.

What Will Happen at the Screening Visit

	Tier 1	Tier 2	Tier 3	Tier 4
Eligibility Review	X			
Informed Consent	X			
Brief Cognitive Screening Exam	X			
Physical/Neurological Exam	X			
Heart Tracing (ECG)	X			
Medical History and Medication Review	X			
Blood Draw	X		X	
MRI		X		
Lumbar Puncture (LP) or Amyloid PET Scan			X	
Optional Sub-Study (Either the LP or Amyloid PET not done at tier 3)				X
Screening visit will be split up into 3-4 visits over 8 weeks. If you do not meet the screening criteria (determined during procedures highlighted in gold) in tier 1, you would not complete tier 2, if you do not meet criteria in tier 2, you would not complete tier 3. If screening criteria in any tier is not met, participation will end.				

What Will Happen during Treatment Period

If determined to be eligible during screening, you will be assigned to one of two arms of the study: 1) receives study medication; 2) receives placebo (a pill or a liquid that looks like medicine but is not real). The following will happen for both:

	Baseline Visit	Weeks 1-24	End of Treatment	45 day Follow-up
Side Effect/Medication Review	X	X	X	X
Physical/Neurological Exam	X	At Week 12	X	X
Heart Tracing (ECG)		At Week 12	X	
Cognitive Testing/Health Surveys	X	At Week 12	X	X
Study Partner Questionnaires	X	At Week 12	X	X
Blood Draw and Vital Signs	X	2x a Week	X	X
Study Partner Injection Training	X			
Injection of study drug	X	5 Days/Week		
Brain MRI	X	At Week 12	X	
Lumbar Puncture and/or Amyloid PET			X	
FDG PET scan	X		X	
There are also optional study procedures not listed here that can be completed. After initial screenings at the CU Anschutz campus in Aurora, CO, participants will be able to have a weekly home nursing visit each week to provide supplies and draw blood (second blood draw will occur at a local Labcorp). Visits to campus during the study will be required for procedures that cannot be done at home.				

Time Spent: The research study (including screening) will take approximately 9 months to complete. Individual visit length will vary based on procedures completed, with the majority of weekly study visits lasting about 90 minutes.

Compensation: Participant will be given $75 at the end of the 24-week treatment period, $25 after the 45 day follow-up, $75 after each lumbar puncture, or $125 after each Amyloid PET scan for a maximum of $500.