Longitudinal Innate Immunity and Aging Study

CLINICALTRIALS.GOV IDENTIFIER	RECRUITMENT STATUS	FIRST POSTED	LAST UPDATE POSTED
NCT03944603	RECRUITING	MAY 9, 2019	MAY 21, 2021

STUDY DESCRIPTION

Brief Summary

This study plans to examine biological bases of cognitive aging. The goals of the study are to better understand how immune system markers, measured in the blood and in the spinal fluid, are related to clinical features of aging over time. The study also aims to better understand how different types of biomarkers may relate to immune health and the aging process. This research may ultimately help us better understand what puts individuals at risk for cognitive decline and for Alzheimer's disease.

Condition or Disease: Healthy Older Adults Ages 60-89

Intervention/treatment:

Phase: N/A

DETAILED DESCRIPTION

N/A

STUDY DESIGN

Study Type: Observational

Estimated Enrollment : 300 participants

Intervention Model : N/A

Masking: N/A

Primary Purpose: N/A

Official Title: Investigating the Contribution of Peripheral Versus Central Nervous System Dysfunction to Cognitive Aging

Actual Study Start Date: April 2019

Estimated Primary Completion Date: March 2024

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OUTCOME MEASURES

Primary Outcome Measures:
1. Levels of Immune Protein Markers in Blood and CSF [Time Frame: 2-Year Changes]
Outcome measures will include longitudinal changes in protein levels of blood inflammation and CSF inflammation
2. Performance on Neuropsychological Measures [Time Frame: 2-Year Changes]
Outcome measures will include longitudinal changes in cognitive measures (e.g., memory and executive functions) over time
3. Levels of Exosomal Innate Immune Markers in Blood and CSF [Time Frame: 2-Year Changes]
Outcome measures will include longitudinal changes in innate immune markers in exosomes (i.e., extracellular vesicles)

Secondary Outcome Measures:
1. Brain Structure [Time Frame: Baseline]
Outcome measures will include baseline structural brain imaging
2. CSF Levels of Alzheimer's Disease Related Markers [Time Frame: 2-year change]
Outcome measures will include CSF levels of proteins associated with Alzheimer's disease pathology

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ELIGIBILITY CRITERIA

Ages Eligible for Study: 60 to 89 Years (Adult, Older Adult)

Sexes Eligible for Study: All

Accepts Healthy Volunteers: Yes

Criteria

Inclusion Criteria:
1. Between ages of 60-89
2. Have a reliable study partner who has frequent contact with the subject (i.e., at least twice per month) and is able to provide information about functional abilities
3. Mini Mental State Examination (MMSE) >23
4. Clinical Dementia Rating (CDR) global score of 0
5. No informant report of significant cognitive decline in prior year
6. No evidence from the screening visit suggesting a neurodegenerative disorder (per team neurologist)
7. Willingness to complete both baseline and 2-year follow-up procedures
Exclusion Criteria:
1. Major psychiatric disorder (e.g. schizophrenia, bipolar disorder, untreated major depression within past year)
2. Neurological conditions affecting cognition (e.g. Parkinson's disease, epilepsy (onset prior than 2 years ago), head trauma with loss of consciousness >5 min within past two years, large vessel infarct, mild cognitive impairment, or dementia)
3. CNS immune conditions and other conditions affecting cognition (e.g., multiple sclerosis, paraneoplastic encephalitides; Hashimoto's encephalopathy; systematic lupus erythematosus)
4. Systematic illness (e.g.,current cancer, renal failure, respiratory failure)
5. Substance abuse/dependence (DSM-V criteria)
6. Current medication use likely to affect CNS (e.g., long-acting benzodiazepines, neuroleptics in the phenothiazine and haloperidol families)
7. Current medication use that precludes lumbar punctures (e.g. anticoagulants, antiplatelets, heparin shots, or some other blood thinner medications: Warfarin [coumadin], Pradaxa [dabigatran], Xarelto [rivaroxaban]. Eliquis [apixaban], or Plavix [clopidogrel].
8. Significant sensory or motor deficits that would interfere with cognitive testing
9. Factors that preclude MR imaging (e.g., pacemaker)
10. Factors that preclude lumbar puncture

CONTACTS AND LOCATIONS

Contacts

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Locations

United States, Colorado	University of Colorado Anschutz Medical Campus	Aurora

Sponsors and Collaborators

University of Colorado, Denver

National Institute on Aging (NIA)

Investigator

MORE INFORMATION

Responsible Party :	University of Colorado, Denver
ClinicalTrials.gov Identifier :	NCT03944603
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Individual Participant Data (IPD) Sharing Statement:	
Plan to Share IPD:	No
Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	No
Keywords provided by University of Colorado, Denver:	*Alzheimer's Disease* *Dementia* *Older Adult COVID-19* *SARS-CoV-2*