WHO CAN PARTICIPATE?

- People ages 55-90 who have been diagnosed with Subjective Cognitive Decline, Mild Cognitive Impairment (MCI) or Mild to Moderate Alzheimer's Disease
- People who are willing to complete all required study procedures

WHAT DOES THE STUDY INVOLVE?

- Over a 8 month period, we will ask you to come in for approximately seven research visits and participate in one phone call. All in-person visits will occur at the MGH Charlestown Navy Yard Campus.
- Study activities include medical and neurological exams, assessments of your memory and thinking, blood draws, taking the study drug daily, and four lumbar punctures.

WANT TO LEARN ABOUT OUR OTHER STUDIES?

ACTRU

Alzheimer's Clinical & Translational Research Unit

CONNECT WITH US

(617)-643-4802

ACTRUSTUDIES@MGH.HARVARD.EDU

OR VISIT OUR WEBSITE:

WWW.ACTRU.ORG

NADALS Basket Trial

A CLINCIAL TRIAL DESIGNED TO EVALUATE THE EFFECTS OF BARICITINIB ON BIOMARKERS OF ALZHEIMER'S DISEASE

WHAT ARE WE STUDYING?

- We are studying the effects of Baricitinib in people with Subjective Cognitive Decline, Mild Cognitive Impairment and Mild to Moderate Alzheimer's Disease. We are looking to measure the levels of Baricitinib present in both the blood and in the cerebral spinal fluid (CSF) and the determine what effect Baricitinib has on biomarkers related to AD. We are hoping that these findings will help us better understand if Baricitinib may be helpful for the treatment of MCI and AD.
- Baricitinib is an oral JAK inhibitor that blocks type I interferon signaling and enzymes involved in inflammation.
- Baricitinib is approved by the FDA at 2 mg and European Medical Agency at 4 mg to treat rheumatoid arthritis. In addition, Baricitinib has been granted emergency use authorization at 4 mg for use on COVID 19 patients.

HOW WILL THE STUDY WORK?

- This is an open-label, biomarker-driven basket trial of Baricitinib. Open-label means that all participants receive the study drug throughout the duration of the study.
- If you choose to participate in this study, you will be asked to come on site for a screening visit to determine your eligibility.
- If you are eligible after the screening visit, you will be asked to come back for 6 additional study visits and participate in 1 follow-up phone call.
- Study procedures will differ depending on the visit; however, study visit activities typically include cognitive tests, blood draws, neurological and physical exams, and ECGs. At screening, baseline, week 8, and week 16 visits, we will collect spinal fluid through a lumbar puncture. You can expect the on-site visits to last between 2-4 hours.
- Participants will take 2 mg of Baricitinib for the first 8 weeks, and then 4 mg of Baricitinib for the following 16 weeks.

WILL I BE PAID FOR ENROLLING IN THE STUDY?

Yes! You will be compensated for each visit that you complete. The cost of parking, transportation, and meal vouchers is included in study compensation.

MEET THE STUDY INVESTIGATOR: DR. ARNOLD!