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Safety and efficacy of Maraviroc in vascular cognitive impairment

This Phase2 clinical trial will study the safety of a FDA-approved HIV drug which may prevent cognitive decline in individuals who have recently experienced a stroke and who are at risk of developing dementia.

Background

Studies show that stroke could increase the risk of developing dementia. Studies have found that blood vessel (vascular) damage in the brain could lead to the loss of cognition (brain function) and the onset of Alzheimer's or other dementia. Vascular dementia is a decline in cognitive skills caused by conditions that block or reduce blood flow to various regions of the brain, depriving them of oxygen and nutrients. After a stroke, which blocks blood flow in the brain, vascular dementia can sometimes occur suddenly or gradually, leading to changes in cognitive skills.

In preliminary results from a large population of individuals who have experienced a stroke, Dr. Einor Ben Assayag's team found that among those who carried a naturally occurring genetic variation in the C-C chemokine receptor 5 (CCR5) gene, the cognitive deficits post stroke were reduced compared to those without the genetic variation. This particular genetic variation in CCR5 has been shown to be protective against HIV. Dr. Ben Assayag's group partnered with other researchers in the field and observed that the Food and Drug Administration-approved HIV drug, Maraviroc impacts the activity of CCR5 and improves cognitive function in a rodent stroke model. In addition, clinical trials by other researchers on individuals with HIV and mild to moderate cognitive impairment have shown that Maraviroc may improve cognitive performance. Dr. Ben Assayag and Dr. Hen Hallevi, Director of the Neurology-Stroke department at the Tel Aviv Sourasky Medical Center Research, will study the impact of the drugs in

individuals who may be at a risk of developing vascular dementia due to stroke.

**Hen Hallavi –
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CADRO
category:
Translational
Research &
Clinical
Interventions

Prior to this
award, Dr. Ben
Assayag received
the 2016
Alzheimer's
Association
Research Grant
award to study
whether blood-
based biomarkers
can be used to
predict who will be
at a risk of
developing
dementia after
stroke.

Research Plan

Drs. Ben Assayag and Hallevi will conduct a Phase 2 clinical trial in 150 individuals aged 50-86 years, who have recently experienced a stroke and have developed mild cognitive impairment (a condition with subtle memory loss that may precede dementia, including Alzheimer's dementia) after stroke. The study will include 3 sites in Israel. Participants in the study will receive the drug at varying doses or placebo (not the actual drug but an inactive substance that has no benefits and also no risk for the participant) for 12 months. The researchers will evaluate the safety of the drug in the participants. Additionally, the team will perform brain scans, cognitive tests as well as collect blood and cerebrospinal fluid samples (a biological fluid found in the brain and spinal cord). Using these measures, the researchers will study brain changes (such as brain function, volume and inflammation) as well as biological markers (biomarkers) associated with dementia in order to evaluate the impact of Maraviroc.

Impact

If successful, the study results may give rise large scale clinical trials and may prevent or reduce cognitive decline in individuals who have experienced stroke.

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