Suzanne Craft, PhD
Wake Forest University School of Medicine
Winston-Salem, NC, USA

2022 Part the Cloud - $795,850.18

A Phase IIA Trial of Empagliflozin and Intranasal Insulin for MCI/AD

This phase IIA clinical trial will look at safety, feasibility and dosing of a combination of insulin and an metabolism targeting drug in individuals with mild cognitive impairment or Alzheimer's disease.

Background

Insulin is a hormone responsible for managing the body's blood sugar levels. Insulin can also be transported to the brain, where it helps maintain nerve cell energy levels and connections between nerve cells. Insulin also plays an important role in the clearance of proteins known to be involved in Alzheimer's. Previous studies have shown a relationship between blood sugar problems and Alzheimer's. Therefore, Dr. Suzanne Craft and colleagues aim to investigate the effects of insulin treatment on Alzheimer's.

Previous clinical trials have shown that insulin delivered through the nose (intranasal) can enter into the cerebrospinal fluid (CSF, a biological fluid that surrounds the brain and spinal cord). A study in a small group of individuals suggested that insulin delivered through the nose over 12 months could potentially improve cognitive function in individuals with Alzheimer's or mild cognitive impairment (MCI), which is a mild form of memory loss. Further, measurement of certain biological markers (biomarkers) in both the CSF and blood have shown that insulin can reduce inflammation and affect biomarkers of Alzheimer's. These studies indicate that treatment with insulin in individuals with Alzheimer's or MCI can improve memory function. In addition, a recent study showed that use of a new anti-diabetic medication, empagliflozin (a drug that lowers blood sugar levels by increasing sugar excreted in urine), reduced the risk of developing dementia in a group of individuals with diabetes.

Research Plan

In a Phase I clinical trial with empagliflozin and insulin, there were promising results in individuals with Alzheimer's or MCI, with no adverse safety effects. To expand on this initial study, Dr. Suzanne Craft and colleagues will conduct a larger, Phase IIA clinical trial to determine the safety, tolerability and dose

of these in combination as well as the feasibility of the combinatory drugs in individuals with Alzheimer's or MCI.

They will recruit 80 participants who will receive intranasal insulin, empagliflozin, a combination of both insulin and empagliflozin, or a placebo (not the actual drug but an inactive substance that has no risk for the participant). The primary outcome measure will consist of any adverse effects to the participants due to the drug treatments. Further, after 1 month of treatment, the researchers will measure changes in memory, changes in biological markers (biomarkers) collected from cerebrospinal fluid (CSF; the biological fluid surrounding the brain and spinal cord) and blood. The researchers will also use brain scan techniques to measure the blood flow in the brain.

Impact

Results from this study will help determine if treatment with already well-studied and safe drugs (insulin and empagliflozin) that affect blood sugar could be used to treat Alzheimer's and/or MCI.

This study was made possible through the generous funding of The Part the Cloud, benefiting the Alzheimer's Association.