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Phase I study of a novel device reducing vascular contributions to dementia

This clinical trial will examine whether a minimally invasive device could reduce damage to the brain blood vessels and reduce the risk of developing dementia.

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Background

Blood vessels in the brain provide nerve cells with vital, oxygen-rich blood that is critical for the cell's ability to function properly. Inadequate blood flow can damage and eventually kill cells anywhere in the body, but the brain is especially vulnerable. Blood vessel stiffness could change the pressure at which blood flows to the brain. Recent studies have highlighted that excessive pressure build up in the blood flowing to the brain could be a risk factor for developing Alzheimer's. This is referred to as "high pulse pressure". Studies show that these high pulse pressures may lead to tiny bleeds in the brain, brain inflammation and these could potentially be associated with the development of dementia. Scientists are trying to understand how to safely reduce the pulse pressure in the brain blood vessels and thereby reduce the risk of cognitive decline.

Dr. David Celermajer and colleagues have developed a minimally invasive device, which is a sophisticated coil applied to a major blood vessel (called "carotid artery" that supplies blood to the brain). The device acts as a "shock absorber" by reducing the pressure of blood flowing through the carotid artery. The device works by slightly altering the shape of the carotid artery and the new shape allows the artery to absorb the excess pressure of the blood flowing into the brain. Using large animals, Dr. Celermajer and colleagues have shown that the device reduces the pressure of blood flowing into the animals' brains. They will now study the applicability of the device in humans.

STUDY

CADRO
 category:
 Translational
 Research & Clinical
 Interventions

Research Plan

Building on preliminary results, Dr. Celermajer's team will conduct a Phase I clinical trial in adults aged 50-75 years who are already undergoing surgery that involves the exposure of carotid artery (such as a surgical procedure to unblock the carotid artery). The surgery is

done to restore normal blood flow to the brain to prevent stroke if individuals exhibit symptoms of reduced brain blood flow.

The researchers will place their device around the carotid artery of the participants for 15 minutes to study the safety and efficiency of the device in reducing the pressure of the blood flowing into the brain without decreasing the brain blood flow. Dr. Celermajer's team will then also assess the safe removal of the device from the participants. In addition, researchers will test for other safety measures of the device by studying its impact on tiny bleeds in the brain, injury to blood vessels, nerve cell death and stroke over a 30-day period after surgery. They will then prepare to test their device in larger clinical trials.

Impact

If successful, the clinical trial may pave the way for reducing damage to the brain blood vessels and thereby could decrease the risk of developing dementia.

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