

Hyperbaric oxygen therapy for cognition in diabetic elderly at high dementia risk

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Country

USA

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Hyperbaric oxygen therapy for cognition in diabetic elderly at high dementia risk

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NIH (NIA)

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01/09/2016

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1

The project/programme is most relevant to:

Alzheimer's disease & other dementias

Keywords

Acquired Cognitive Impairment... Aging... Alzheimer's Disease... Alzheimer's Disease Related Dementias (ADRD)... Alzheimer's Disease including Alzheimer's Disease Related Dementias (AD/ADRD)... Behavioral and Social Science... Brain Disorders... Cerebrovascular... Clinical Research... Clinical Research - Extramural... Clinical Trials and Supportive Activities... Dementia... Diabetes... Diagnostic Radiology... Effectiveness Research... Endocrine System...

Research Abstract

Abstract This resubmission responds to “PAR-16-365-Pilot Clinical Trials for the Spectrum of Alzheimer’s Disease and Age-related Cognitive Decline (R01)”. It will examine the efficacy of hyperbaric oxygen therapy (HBOT) in improving cognitive functioning in cognitively impaired elderly with diabetes (T2D), who have high risk for dementia. It is a collaboration of the Icahn School of Medicine at Mount Sinai, NY, the University of Wisconsin, the Sagol Center for Hyperbaric Medicine and Research at Asaf Harofeh Medical Center, Israel—one of the world’s largest and busiest hyperbaric units—and the Sheba Medical Center, Israel. HBOT is a treatment in which oxygen-enriched air (up to 100%) is administered to patients at a pressure above the ambient atmosphere. The combined action of hyperoxia and hyperbaric pressure leads to significant improvements in tissue oxygenation, resulting in cerebrovascular benefits with improved ischemic damage and cerebral blood flow. Recently, our group published compelling evidence from clinical trials indicating HBOT neurotherapeutic effects in stroke, with better cognitive function and elevated brain activity in SPECT. New preliminary data suggests potential neurotherapeutic effects of HBOT on T2D elderly with mild cognitive impairment (MCI), showing better cognitive performance and brain activity. We propose a randomized controlled clinical trial examining the short (12 weeks) and long-term (12 months) efficacy of HBOT. We will test hypotheses that HBOT compared to a sham condition improves cognitive function and increases cerebral blood flow and glucose utilization in MCI patients with T2D. Such patients are at high dementia risk and enriched in cerebrovascular disease, and thus have high potential for benefitting from HBOT. Aim 1 examines the potential beneficial effects of HBOT on cognition (with a primary composite measure of executive functions and episodic memory, both affected by T2D). Aim 2 examines effects of HBOT on ischemic injury which will be measured by CBF at the level of capillaries in gray matter (by MRI arterial spin labeling), and in macrovessels (by a novel 4D Flow MRI technology developed by our group). Aim 3 focuses on effects of HBOT on cerebral glucose utilization using [F18]FDG-PET. Finally, Aim 4 investigates mediation by the biomarkers, i.e. whether their inclusion in a mediation model will attenuate the effect of HBOT on cognition, suggesting them as underlying mechanisms. This study will be performed in Israel, where there is optimal infrastructure and expertise for all the study components at significantly lower costs. HBOT can be widely deployed in the US so if successful, this pilot study will provide the basis for a multi-center large-scale clinical trial for definitive evidence of its benefits to cognition in T2D patients at high dementia risk. Despite advances in our understanding of risk factors and the pathologic basis for dementia, treatments are of very limited effects. As the proportion of elderly increases, the accelerating prevalence of T2D and dementia amplifies this application’s public health impact.

Lay Summary

Narrative An urgent need exists to identify effective interventions to arrest or reverse dementia and cognitive loss at its earliest stages. The proposed pilot randomized clinical trial will investigate the short and long-term effects of hyperbaric oxygen therapy on cognitive functioning, cerebral blood flow, and glucose uptake in diabetic elderly with mild cognitive impairment. and provide the basis for a large-scale multi-center study of hyperbaric oxygen therapy effects on cognition in diabetes. The potential to preserve, or even enhance, cognition in elderly at high risk of cognitive decline and dementia has major implications for the affected individuals and their support systems that bear the social and financial burdens of long-term

caregiving.

Further information available at:

Types:

Investments > €500k

Member States:

United States of America

Diseases:

Alzheimer's disease & other dementias

Years:

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