

Molecular Hydrogen for Cognitive Function and Performance in Elderly



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ClinicalTrials.gov Identifier: NCT02830854

Recruitment Status : Completed

First Posted : July 13, 2016

Last Update Posted : October 28, 2016

Sponsor:

University of Novi Sad, Faculty of Sport and Physical Education

Information provided by (Responsible Party):

University of Novi Sad, Faculty of Sport and Physical Education

- **Study Details**

- [Tabular View](#)
- [No Results Posted](#)

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Study Description

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Brief Summary:

A variety of non-pharmacological interventions have been used in the management of Alzheimer's disease (AD) and similar cognitive disorders in elderly, yet no therapeutic modality has demonstrated conclusive positive results in terms of effectiveness. Although it is still unknown what triggers AD, recent studies have shown that AD is associated with brain energy depletion, oxidative stress, and mitochondrial dysfunction. Since supplemental molecular hydrogen (H₂) supports cell energy production and acts as a highly bioavailable mitochondria-related antioxidant, it may provide an ideal agent to facilitate treatment and perhaps prevention of AD and similar cognitive disorders in elderly. The overall hypothesis to be evaluated in this project is that administration of H₂ will positively affect patient-reported outcomes and clinical biomarkers in men and women suffering from AD.

Condition or disease	Intervention/treatment	Phase
Cognitive ImpairmentsAging	Other: Molecular Hydrogen	Phase 3

Study Design

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Study Type : Interventional (Clinical Trial)

Actual Enrollment : 13 participants

Intervention Model: Single Group Assignment

Masking: None (Open Label)

Primary Purpose: Supportive Care

Study Start Date : July 2016

Actual Primary Completion Date : September 2016

Actual Study Completion Date : September 2016

Arms and Interventions

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Arm	Intervention/treatment
Experimental: Molecular Hydrogen Molecular hydrogen: 20 min per day of 3% H2 during 4 weeks	Other: Molecular Hydrogen

Outcome Measures

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Primary Outcome Measures :

1. ADAS-Cog score for cognitive function [Time Frame: Change from Baseline ADAS-Cog Score at 4 weeks]

ADAS-Cog total score and scores for 4 separate cognitive domains (memory, orientation, praxis, and language) will be evaluated.

Eligibility Criteria

Ages Eligible for Study: 65 Years and older (Older Adult)
Sexes Eligible for Study: All
Accepts Healthy Volunteers: Yes

Criteria

Inclusion Criteria:

- Age over 65
- No psychiatric comorbidities

Exclusion Criteria:

- Use of dietary supplements 4 weeks before study commence

Contacts and Locations

Locations

Serbia

Applied Bioenergetics Lab at Faculty of Sport and PE
Novi Sad, Vojvodina, Serbia, 21000

Sponsors and Collaborators

University of Novi Sad, Faculty of Sport and Physical Education

More Information

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Publications:

[Ostojic SM. Molecular hydrogen: An inert gas turns clinically effective. Ann Med. 2015 Jun;47\(4\):301-4. doi: 10.3109/07853890.2015.1034765. Epub 2015 May 4. Review.](#)

[Ostojic SM. Targeting molecular hydrogen to mitochondria: barriers and gateways. Pharmacol Res. 2015 Apr;94:51-3. doi: 10.1016/j.phrs.2015.02.004. Epub 2015 Feb 24. Review.](#)

[Ohno K, Ito M, Ichihara M, Ito M. Molecular hydrogen as an emerging therapeutic medical gas for neurodegenerative and other diseases. Oxid Med Cell Longev. 2012;2012:353152. doi: 10.1155/2012/353152. Epub 2012 Jun 8. Review.](#)

Responsible Party: University of Novi Sad, Faculty of Sport and Physical Education

ClinicalTrials.gov Identifier: [NCT02830854](#) [History of Changes](#)

Other Study ID Numbers: DK-DR16-02

First Posted: July 13, 2016 [Key Record Dates](#)

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Last Verified: October 2016

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD: Undecided

Additional relevant MeSH terms:

Cognitive Dysfunction
Cognition Disorders
Neurocognitive Disorders
Mental Disorders