

 This is the classic website, which will be retired eventually. Please visit the modernized ClinicalTrials.gov instead.

Notice to API users: Read about imminent changes impacting usage of the [ClinicalTrials.gov API](#).

 U.S. National Library of Medicine

ClinicalTrials.gov



Hydrogen-rich Water for Non-alcoholic Fatty Liver Disease



The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our [disclaimer](#) for details.

ClinicalTrials.gov Identifier: NCT03625362

[Recruitment Status](#) ⓘ : Completed

[First Posted](#) ⓘ : August 10, 2018

[Last Update Posted](#) ⓘ : April 16, 2019

[View this study on the modernized ClinicalTrials.gov](#)

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](#)

[Disclaimer](#)

[How to Read a Study Record](#)

Study Description

Go to 

Brief Summary:

This study evaluates how 4-week supplementation with hydrogen-rich water affects liver fat accumulation, blood lipid profiles and body composition in patients with non-alcoholic fatty liver disease

| <u>Condition or disease</u> ⓘ | <u>Intervention/treatment</u> ⓘ | <u>Phase</u> ⓘ |
|-----------------------------------|---|----------------|
| Non-Alcoholic Fatty Liver Disease | Dietary Supplement: Hydrogen Dietary Supplement: Placebo | Not Applicable |

Detailed Description:

Non-alcoholic fatty liver disease (NAFLD) is a metabolic disorder characterized by liver fat deposition due to causes other than excessive alcohol consumption. NAFLD can cause many liver dysfunction-related symptoms and signs, with the disease may progress to non-alcoholic steatohepatitis, a condition marked by liver inflammation, fibrosis and irreversible damage. NAFLD is usually accompanied by insulin resistance and obesity, with up to 30% of population in industrialized countries have NAFLD. While NAFLD is rapidly becoming the most common liver disease worldwide, its treatment remains elusive, and directed toward correction of the risk factors. Since metabolic impairment plays a major role in NAFLD pathogenesis, any agent that advance lipid and glucose metabolism could be appropriate to tackle this complex condition. Molecular hydrogen (H₂) has recently emerged as a novel pro-metabolic agent that might positively affect liver health. Supplemental hydrogen improves blood lipid profiles and insulin resistance in overweight women, patients with type 2 diabetes, and in subjects with potential metabolic syndrome. In addition, drinking hydrogen-rich water reduces hepatic oxidative stress and alleviated fatty liver damage in rodents. However, no human studies so far evaluated its effectiveness to alter liver steatosis in patients with NAFLD. In this pilot trial, we analyze the effects of 4-week hydrogen-rich water intake on liver fat deposition, body composition and lab chemistry profiles in overweight patients suffering from NAFLD.

Study Design

Go to

Study Type ⓘ :

Interventional (Clinical Trial)

Actual Enrollment ⓘ :

10 participants

Allocation:

Randomized

Intervention Model:

Crossover Assignment

Masking:

Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Primary Purpose:

Supportive Care

Official Title:

Effects of Hydrogen-rich Water on Liver Fat Accumulation, Blood Lipids and Body Fatness in Patients With Non-alcoholic Fatty Liver Disease

Actual Study Start Date ⓘ :

September 1, 2018

Actual Primary Completion Date ⓘ :

December 31, 2018

Actual Study Completion Date ⓘ :

December 31, 2018

Resource links provided by the National Library of Medicine



[MedlinePlus Genetics](#) related topics: [Non-alcoholic fatty liver disease](#)

[MedlinePlus](#) related topics: [Drinking Water](#) [Fatty Liver Disease](#) [Liver Diseases](#)

[Genetic and Rare Diseases Information Center](#) resources: [Visceral Steatosis](#)

[U.S. FDA Resources](#)

Arms and Interventions

Go to

| Arm ⓘ | Intervention/treatment ⓘ |
|--|---|
| Experimental: Hydrogen 1 L of hydrogen-rich water | Dietary Supplement: Hydrogen Hydrogen-rich water |
| Placebo Comparator: Placebo 1 L of tap water | Dietary Supplement: Placebo Tap water |

Outcome Measures

Go to

[Primary Outcome Measures](#) ⓘ :

1. Liver fat content [Time Frame: Change from baseline liver triglycerides at 4 weeks]

MRS spectra for liver triglycerides

Secondary Outcome Measures :

1. Total cholesterol [Time Frame: Change from baseline total cholesterol at 4 weeks]

Level of total cholesterol in the blood

2. Total body fatness [Time Frame: Change from baseline fat percentage at 4 weeks]

Fat percentage evaluated by BIA

Eligibility Criteria

Go to

Information from the National Library of Medicine



Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, [Learn About Clinical Studies](#).

Ages Eligible for Study:

18 Years to 65 Years (Adult, Older Adult)

Sexes Eligible for Study:

All

Accepts Healthy Volunteers:

No

Criteria

Inclusion Criteria:

- Age \geq 18 years
- Body mass index $>$ 25 kg/m²
- Free of major diseases besides NAFLD
- Must be able to give written informed consent

Exclusion Criteria:

- Use of any dietary supplements within 4 weeks before study commences
- Abnormal values for lab clinical chemistry ($>$ 2 SD)

Information from the National Library of Medicine

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

*Please refer to this study by its ClinicalTrials.gov identifier (NCT number): **NCT03625362***

Locations**Serbia**

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

FSPE Applied Bioenergetics Lab
Novi Sad, Vojvodina, Serbia, 21000

Sponsors and Collaborators

University of Novi Sad, Faculty of Sport and Physical Education

More InformationGo to **Publications:**

[Kajiyama S, Hasegawa G, Asano M, Hosoda H, Fukui M, Nakamura N, Kitawaki J, Imai S, Nakano K, Ohta M, Adachi T, Obayashi H, Yoshikawa T. Supplementation of hydrogen-rich water improves lipid and glucose metabolism in patients with type 2 diabetes or impaired glucose tolerance. Nutr Res. 2008 Mar;28\(3\):137-43. doi: 10.1016/j.nutres.2008.01.008.](#)

[Nakao A, Toyoda Y, Sharma P, Evans M, Guthrie N. Effectiveness of hydrogen rich water on antioxidant status of subjects with potential metabolic syndrome-an open label pilot study. J Clin Biochem Nutr. 2010 Mar;46\(2\):140-9. doi: 10.3164/jcbrn.09-100. Epub 2010 Feb 24.](#)

[Korovljević D, Trivić T, Drid P, Ostojic SM. Molecular hydrogen affects body composition, metabolic profiles, and mitochondrial function in middle-aged overweight women. Ir J Med Sci. 2018 Feb;187\(1\):85-89. doi: 10.1007/s11845-017-1638-4. Epub 2017 May 30.](#)

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Korovljević D, Stajler V, Ostojic J, LeBaron TW, Ostojic SM. Hydrogen-rich water reduces liver fat accumulation and improves liver enzyme profiles in patients with non-alcoholic fatty liver disease: a randomized controlled pilot trial. Clin Res Hepatol Gastroenterol. 2019 Nov;43(6):688-693. doi: 10.1016/j.clinre.2019.03.008. Epub 2019 Apr 11.

Responsible Party:

University of Novi Sad, Faculty of Sport and Physical Education

ClinicalTrials.gov Identifier:

[NCT03625362](#) [History of Changes](#)

Other Study ID Numbers:

0417-HRW/2018

First Posted:

August 10, 2018 [Key Record Dates](#)

Last Update Posted:

April 16, 2019

Last Verified:

April 2019

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD:

Undecided

Plan Description:

IPD will be shared via Institutional repository

Studies a U.S. FDA-regulated Drug Product:

No

Studies a U.S. FDA-regulated Device Product:

No

Additional relevant MeSH terms:

Liver Diseases

Fatty Liver

Non-alcoholic Fatty Liver Disease

Digestive System Diseases