Clinical Trial Details (PDF Generation Date :- Thu, 01 Dec 2022 02:55:50 GMT)

CTRI Number	CTRI/2018/03/012487 [Registered on: 12/03/2018] - **Trial Registered Prospectively**
Last Modified On	17/12/2018
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Nutraceutical
Study Design	Randomized, Parallel Group, Placebo Controlled Trial
Public Title of Study	Effects of Hydrogen Rich Water on Risk Factors of Heart Disease and Diabetes.
Scientific Title of Study	Effects of Hydronen Magnesium Tablets on Cardiometabolic Risk Factors and Inflammation in Subjects with Metabolic Syndrome.

Secondary IDs if Any

Secondary ID	Identifier
NIL	NIL

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	Dr R B Singh
Designation	Director Research,
Affiliation	Halberg Hospital and research Institute
Address	Department of Medicine, Division of Research, Room 1, Civil Lines,Opp.Wilsonia College, Moradabad (UP) Department of Medicine,Division of Research,Room 1. Moradabad UTTAR PRADESH 244001 India
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Details Contact Person (Scientific Query)

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Source of Monetary or Material Support

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> President, Natural Wellness Now Health Products Inc. #106 555 Foster Ave, Coquitlam BC, V3J 0B6 Canada. Email alextarnava@gmail.com

Primary Sponsor

Primary Sponsor Details	
Name	Natural Wellness Now Health Products Inc
Address	Natural Wellness Now Health Products Inc. #106 555 Foster Ave, Coquitlam BC, V3J 0B6 Canada. Email alextarnava@gmail.com
Type of Sponsor	Pharmaceutical industry-Global

Details of Secondary Sponsor

Name	Address
International College of Nutrition	Civil Lines,Opp.Wilsonia College,Moradabad (UP)244001

Countries of Recruitment

List of Countries
India
Slovakia

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr R B Singh	Halberg Hospital and Research Institute	Department of Medicine, Outdoor Room 1,Civil Lines, Opp. Wilsonia College,(UP) Civil Lines, Opp. wilsonia College Moradabad UTTAR PRADESH	9997794102 rbs@tsimtsoum.net

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Halberg Hospital and Research Institute Ethic Committee	Approved	07/03/2018	No

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Healthy Human Volunteers	Metabolic Syndrome

Intervention / Comparator Agent

Type	Name	Details
Intervention	Hydrogen-manesium tablets	Active ingredient: Hydrogen-Rich Water (HRW). HRW is made with a H2-producing tablet that contains non-ionic metallic magnesium with organic acids (malic and tartaric). IT also contains small amount of dextrose (200 mg), and the lubricant PRUV (Sodium Stearyl Fumarate), which is a commonly used lubricating agent for tablets and other

		products. There are no indications that it is toxic, and it is approved as GRAS by the FDA. The active magnesium reacts with water to produce molecular hydrogen (H2) and magnesium hydroxide [Mg(OH)2] according to the reaction: Mg + 2H2O -- H2 + Mg(OH)2. The magnesium hydroxide is then neutralized by the organic acids leaving magnesium ions and their conjugate bases (Mg(OH)2 + malic acid/tartaric acid -- Mg2+ + malate + tartrate). The amount of Mg in each tablet is 80mg, which is well below the daily reference intake (DRI), and upper limit, thus avoiding any adverse events from magnesium ingestion. (https://ods.od.nih.gov/factsheets/Magnesium-HealthProfessional/).and inactive placebo tabs.
Comparator Agent	Placebo tablets	Identical placebo tablets with inactive agent

Inclusion Criteria

Inclusion Criteria	
Age From	30.00 Year(s)
Age To	60.00 Year(s)
Gender	Both
Details	Inclusion criteria: Adults aged 30-60 years without recent AMI or stroke, with any of the three markers of metabolic syndrome; prehypertension, prediabetes and central obesity or dyslipidemia. Criteria of diagnosis. Prehypertension would be considered in presence of systolic BP 130-139 mm HG and diastolic 85-89 mm Hg. Pre-diabetes would be considered in presence of fasting blood glucose 110-125 mg/dl. Central obesity would be considered in presence of waste circumference of 100 mm in women and 90 mm among men.

Exclusion Criteria

Exclusion Criteria	
Details	Exclusion criteria: cancer, chronic dysentery, HIV

Method of Generating Random Sequence	Computer generated randomization
Method of Concealment	An Open list of random numbers
Blinding/Masking	Participant, Investigator and Outcome Assessor Blinded

Primary Outcome

Outcome	Timepoints
Primary: Effects of h2 magnesium tablets on various markers of metabolic syndrome; blood pressures, blood glucose and central obesity,triglycerides and HDL cholesterol as well as hsCRP along with parameters of oxidative stress; TBARS,MDA, diene conjugates	Baseline After 4 weeks After 12 weeks After 24 weeks

Secondary Outcome

Outcome	Timepoints
Secondary: effects on IL-6,IL-1,TNF-alpha,IL-10,	Baseline and after 12 or 24 weeks,if funds

	NFkbeta, MMPs,leptin, cortisol available
Target Sample Size	**Total Sample Size=**120 **Sample Size from India=**60 **Final Enrollment numbers achieved (Total)=**Applicable only for Completed/Terminated trials **Final Enrollment numbers achieved (India)=**Applicable only for Completed/Terminated trials
Phase of Trial	Phase 2
Date of First Enrollment (India)	01/05/2018
Date of First Enrollment (Global)	01/05/2018
Estimated Duration of Trial	**Years=**0 **Months=**6 **Days=**0
Recruitment Status of Trial (Global)	Not Yet Recruiting
Recruitment Status of Trial (India)	Not Yet Recruiting
Publication Details	Design of study would be presented at Cardiovascular Scicences congress, Bratislava May 2018
Brief Summary	Please let me know how to paste the summary? Randomized,double blind controlled trial with with molecular hydrogen in metabolic syndrome. Follow up 12 or 24 weeks Parameters; blood lipids, hsCRP, blood glucose, TBARS,MDA,diene conjugate Similar study is planned at Bratislava in Slovakia