Clinical Trial Details (PDF Generation Date :- Thu, 20 Apr 2023 03:23:11 GMT)

CTRI Number	CTRI/2021/02/031066 [Registered on: 08/02/2021] - **Trial Registered Prospectively**
Last Modified On	17/03/2022
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Ayurveda Nutraceutical
Study Design	Randomized, Parallel Group, Placebo Controlled Trial
Public Title of Study	Clinical trial on overweight adult healthy volunteers
Scientific Title of Study	A randomized, double blind, parallel assignment, placebo-controlled, two arm study to evaluate the safety and efficacy of iPulse (multi fruit blend juice) in overweight adult healthy volunteers

Secondary IDs if Any

Secondary ID	Identifier
RRS/CL/IPL/OW/2020 Version 1.0 dated 16th Mach 2020	Protocol Number

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

Details of Principal Investigator	
Name	Dr Ashok Godavarthi
Designation	CEO
Affiliation	Radiant Research services pvt. Ltd.
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Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
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Designation	CEO
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Details Contact Person (Public Query)

Details Contact Person (Public Query)	
Name	Dr Balu kolar
Designation	Manager-Product developement
Affiliation	INDUS VIVA HEALTH SCIENCES PVT.LTD
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Source of Monetary or Material Support

Source of Monetary or Material Support
> IndusViva HealthSciences Pvt. Ltd., Nandi Durga Rd, Jayamahal Extension, Benson Town, Bengaluru, Karnataka 560046

Primary Sponsor

Primary Sponsor Details	
Name	IndusViva HealthSciences Pvt Ltd
Address	Nandi Durga Rd, Jayamahal Extension, Benson Town, Bengaluru, Karnataka 560046
Type of Sponsor	Other [Health & Wellness Company]

Details of Secondary Sponsor

Name	Address
NIL	NIL

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
DrShubarani	Sushrutha Ayurvedic Medical College And Hospital	Ground Floor Room nuber 3 Prashanti Kuteera jodi Bingipura, Jigani Hobli, Anekal, Taluk, Bengaluru, Karnataka 560105 Bangalore KARNATAKA	9449453674 dr.shubharani111@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Shettys Hospital -Ethics committee	Approved	26/01/2021	No

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Healthy Human Volunteers	Over weight
Patients	Overweight

Intervention / Comparator Agent

Type	Name	Details
Intervention	i-Pulse (rich multi fruit blend juice)	Day 0 to Day 60 Route of administration: orally Dosage form: liquid Duration : 90 days Dose:30 ml Frequency: twice daily Before break fast and Dinner
Comparator Agent	Placebo (Oral juice)	Day 0 to Day 60 Route of administration: orally Dosage form: liquid Duration : 90 days Dose:30 ml Frequency: twice daily Before break fast and Dinner

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	55.00 Year(s)

Gender	Both
Details	1) Age/sex: men and women (1:1, equal distribution) aged 18-55 years (Preferably subgroup of age 18-35 and age 36-55, if feasible) 2) Subject with BMI 25-30 kg/m2 3) Subjects who perceive themselves to be under stress and having a score of 14-24 on the Perceived Stress Scale (PSS). 4) Healthy subjects as determined by: Medical history, Physical examination and Clinical judgment of the investigator 5) Subject willing to provide written informed consent and comes for regular follow up. 6) Subjects who agree to stop from using supplements during the study 7) Subjects willing to follow the suggested diet plan

Exclusion Criteria

Exclusion Criteria	
Details	1) Female subjects who are pregnant, lactating or planning to become pregnant during the study period. 2) Known history of any chronic illness taking regular pharmacological agents. 3) Significant Gastrointestinal (i.e. inflammatory bowel disease, celiac), liver or kidney disease 4) Cardiac condition that compromises normal function (e.g. mitral valve disease, heart failure) 5) History of major cardiovascular events in the last 1 year (stroke or myocardial infraction) 6) History of drug dependence or any severe co-morbid medical conditions. 7) High alcohol intake (>2 standard drinks per day) or use of recreational drugs (such as cocaine, methamphetamine, marijuana, etc., Nicotine/Caffeine dependence. 8) Administration of any other multivitamins/herbal product/wellness products 9) Subject has participated in a clinical study within the last 30 days prior to entering this study.

Method of Generating Random Sequence	Computer generated randomization
Method of Concealment	Case Record Numbers
Blinding/Masking	Participant, Investigator and Outcome Assessor Blinded

Primary Outcome

Outcome	Timepoints
1. Primary Measurement will be the safety and tolerability of iPulse through Laboratory Parameters	Baseline, 4 weeks and 8 weeks

Secondary Outcome

Outcome	Timepoints
2. Secondary Measurement will be to assess the efficacy of I-Pulse through Demographics (Body weight, BMI, Waist circumference)	Day 0,Day 45 and Day 90

Target Sample Size	**Total Sample Size=**80 **Sample Size from India=**80 **Final Enrollment numbers achieved (Total)=**80 **Final Enrollment numbers achieved (India)=**80
Phase of Trial	Phase 3/ Phase 4
Date of First Enrollment (India)	08/02/2021
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**0 **Months=**6 **Days=**0

Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Completed
Publication Details	NIL
Brief Summary	Obesity and metabolic syndrome are considered to be major public health crises not only in the United States but also globally. An expert panel convened by the National Institutes of Health has defined overweight as a body mass index (BMI) of 25 to 29.9 kg/m2 and obesity as a BMI of 30 kg/m2 or greater. According to the World Health Organization (WHO), as of 2005 there were approximately 1.6 billion overweight adults globally, of whom at least 300 million were clinically obese. The prevalence of overweight and obese American adults has steadily increased over the years in both genders, at all ages, in all racial and ethnic groups, at all educational levels, and for all smoking levels. Most studies show an increase in mortality rates associated with obesity. Individuals who are obese have a 10%–50% increased risk of death from all causes, compared with healthy-weight individuals. Most of the increased risk is due to cardiovascular causes. Obesity is associated with about 112,000 excess deaths per year in the U.S. population relative to healthy-weight individuals. iPulse has numerous effects on the body. iPulse contains a rich blend of antioxidant fruits which mainly protects us from numerous diseases for wellbeing and healthy life. It prevents us from the neurodengerative problems, supports healthy memory, helps to prevent respiratory related problem, improves resistance against allergies, protection of liver, controls the homeostasis level, helps reduce GI problems, it maintains healthy vision, improves circulation in the eyes, helps to synthesis of plasma cells (WBS, RBC and platelets), supports healthy haemoglobin level and healthy immunity