FULL DETAILS (Read-only) -> Click Here to Create PDF for Current Dataset of Trial

CTRI Number	**CTRI/2020/09/027806** [Registered on: 15/09/2020] **Trial Registered Prospectively**
Last Modified On:	17/03/2022
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Ayurveda
Study Design	Randomized, Parallel Group, Multiple Arm Trial
Public Title of Study	Clinical trial on iCofeee product in healthy subjects
Scientific Title of Study	A randomized, multi-centre, double blind, placebo-controlled, three arm study to evaluate the safety and efficacy of iCoffee in maintaining or managing post-prandial blood glucose levels in healthy volunteers
Trial Acronym	

Secondary IDs if Any

Secondary ID	Identifier
RRS/CL/ICO/BG/2020 Version 1.0 dated 23 Mar 2020	Protocol Number

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

Name	Dr Ashok Godavarthi
Designation	C.E.O
Affiliation	Radiant research services pvt. Ltd.
Address	Radiant research services pvt. Ltd. Plot No:99 A, 8th Main Road, III Phase, Peenya Industrial Area, Bengaluru, 560058, Karnataka, India. Bangalore KARNATAKA 560058, India
Phone	9880999297
Fax	
Email	ashok@radiantresearch.in

Details of Contact Person Scientific Query

Name	Dr Ashok Godavarthi
Designation	C.E.O
Affiliation	Radiant research services pvt. Ltd.
Address	Radiant research services pvt. Ltd. Plot No:99 A, 8th Main Road, III Phase, Peenya Industrial Area, Bengaluru, 560058, Karnataka, India. Bangalore KARNATAKA 560058, India
Phone	9880999297
Fax	
Email	ashok@radiantresearch.in

Details of Contact Person

Name	Dr Balukolar

Public Query

Designation	Manager-Product developement
Affiliation	IndusViva HealthSciences Pvt. Ltd.
Address	Indus Viva Health Sciences Pvt. Ltd. Nandi Durga Rd, Jayamahal Extension, Benson Town, Bengaluru, Karnataka 560046 Bangalore KARNATAKA 560046 India
Phone	9902557065
Fax	
Email	dr.balu@indusviva.com

Source of Monetary or Material Support

IndusViva HealthSciences Pvt. Ltd., Nandi Durga Rd, Jayamahal Extension, Benson Town, Bengaluru, Karnataka 560046

Primary Sponsor

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

India

Sites of Study Modification(s)

No of Sites = **2**

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr Chikkalingaiah Siddegowda	Medstar Hospital	614, 171/3, Kodigehalli Main Rd, Shanthivana, Sanjeevini Nagar, Bengaluru, Karnataka 560092 Ground floor Department of general medicine Room no: 2 Bangalore KARNATAKA	9844004187 drchikkalingaiahmedstar@gmail.com
Dr A Gopal Rao	Rajiv Gandhi Institute of Medical Sciences	Dept. of general medicine, Room no 13, First floor, Shanti Nagar Colony,	9912320517 drgopalraoa@gmail.com

		Balaga, Srikakulam, Andhra Pradesh 532001 Srikakulam ANDHRA PRADESH Srikakulam ANDHRA PRADESH	

Details of Ethics Committee Modification(s)

No of Ethics Committees= **2**

Name of Committee	Approval Status
Institutional Ethics Committe Medical college & Government General Hospital - Government	Approved
Medstar Speciality Hospital Ethics Committee	Approved

Regulatory Clearance Status from DCGI

Status
Not Applicable

Health Condition / Problems Studied

Health Type	Condition
Healthy Human Volunteers	General health

Intervention / Comparator Agent

Type	Name	Details
Intervention	Group I – iCoffee	Dose: 1 sachet twice a day 100-120 ml hot water Dosage : blend-based product Route of administration: Orally Duration:90 days
Intervention	Group II- Salcital®	Dose: 1 sachet twice a day 100-120 ml hot water Dosage : blend-based product Route of administration: Orally Duration:90 days
Comparator Agent	Group III – Placebo	Dose: 1 sachet twice a day 100-120 ml hot water Dosage : blend-based product Route of administration: Orally Duration:90 days

Inclusion Criteria

Age From	18.00 Year(s)
Age To	55.00 Year(s)
Gender	Both
Details	1. Adult males and non-pregnant females aged 18 to 55 years 2. Subjects who agree to stop from using supplements during the study period 3. Willing to give inform consent form 4. Subjects willing to follow the suggested diet plan. 5. Having a diagnosis of pre-diabetes (impaired fasting glucose or impaired glucose tolerance) and meeting one of the following criteria i. Fasting Plasma Glucose 100 to 125 mg/dL, fasting is defined as no caloric intake for at least 8 h, OR ii. 2-h Post load Glucose 140 to 199 mg/dL during an OGTT. The test should be performed as described by the WHO, using a glucose load containing the equivalent of 75 g anhydrous glucose dissolved in water.OR iii. Glycosylated hemoglobin (A1C) 5.7 to 6.4%. The test should be

	performed in a laboratory using a method that is NABL certified. 6. Subject with BMI ≥ 25 kg/m2

ExclusionCriteria	**Details**	1. History of Type I or Type II Diabetes Mellitus 2. A know history or present condition of allergic response to any pharmaceutical products and supplements 3. Any history suggestive of micro vascular or macro vascular disease 4. Administration of any form of pharmacotherapy for the management of pre-diabetes in last 3 months. 5. Impaired renal function; eGFR<60mls/min/1.73m2. 6. Known history of any chronic illness taking regular pharmacological agents. 7. Women in child bearing age unable to practice any form of contraception 8. Subjects who are pregnant or lactating 9. Subjects on herbal supplements/any other wellness product 10. History of alcohol, tobacco, substance or drug abuse 11. Subject who has participated in a clinical study within the last 30 days prior to entering this study. 12. Subject with hypersensitivity to any of the ingredients of the study products. 13. Refusing consent or physician uncomfortable with patient compliance to treatments or follow up.

Method of Generating Random Sequence	Computer generated randomization
Method of Concealment	Case Record Numbers
Blinding/Masking	Double Blind Double Dummy

Primary Outcome

Outcome	TimePoints
Laboratory Parameters Hematology, Biochemistry, liver profile, Kidney profile, Lipid Profile, Urine analysis, FBS, Body Weight & ECG at Screening (- 7-0 day) and end of the Study (90 day). Biomarkers: hsCRP and IL-6 levels at Baseline (0 day) and end of the Study (90 day).	Day 0 and Day 90

Secondary Outcome

Outcome	TimePoints
1.Blood glucose levels (FBS &PPBS) 2.Glycosylated Haemoglobin (HbA1C) 3.2h-OGTT 4.Insulin Sensitivity Index 5.Serum Insulin 6.Mental Alertness measure with ZOGIM-A or other standardized questionnaire	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)	18/09/2020
Date of Study Completion (India)	07/01/2022
Date of First Enrollment (Global)	Date Missing
Date of Study Completion (Global)	Date Missing
Estimated Duration of Trial	**Years=**"0" **Months=**"9" **Days=**"0"
Recruitment Status of Trial (Global) Modification(s)	Not Applicable
Recruitment Status of Trial (India)	Completed
Publication Details	NIL
Individual Participant Data (IPD) Sharing Statement	**Will individual participant data (IPD) be shared publicly (including data dictionaries)?** **Response** - NO
Brief Summary	The Coffee (*Coffea arabica* L.) beans are rich in bioactive compounds of interest for human health and cosmetics. Coffee has been claimed as a functional beverage being an important source of antioxidants in human diet, especially due to the high amounts of phenolic compounds, caffeine, alkaloids, terpenoids, carotenoids, inorganic substances and vitamins. It also consists of carbohydrates, lipids, volatile and heterocyclic compounds. *C. Arabica* extracts have revealed a set of important biological activities, such as antioxidant, antibacterial, antiviral, anti-inflammatory, suppressive activity of metalloproteinase expression and reduction of oxidative damage to macromolecules. Secondary metabolites have presented relevant biological activities as, for instance, stimulation of the central nervous system, diuretic and peripheral vasoconstriction. Caffeine present in coffee inhibits glucose uptake in adipose tissue

Close

FULL DETAILS (Read-only) -> Click Here to Create PDF for Current Dataset of Trial

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 Modification(s)	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
Trial Acronym	

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)

Name	Dr Ashok Godavarthi
Designation	CEO
Affiliation	Radiant Research services pvt. Ltd.
Address	Plot No:99/A, 8th Main Road, III Phase, Peenya Industrial Area, Bengaluru, 560058, Karnataka, India. Bangalore KARNATAKA 560058 India
Phone	9880999297
Fax	
Email	ashok@radiantresearch.in

Details of Contact Person Scientific Query

Name	Dr Ashok Godavarthi
Designation	CEO
Affiliation	Radiant Research services pvt. Ltd.
Address	Plot No:99/A, 8th Main Road, III Phase, Peenya Industrial Area, Bengaluru, 560058, Karnataka, India. KARNATAKA 560058 India
Phone	9880999297
Fax	
Email	ashok@radiantresearch.in

Details of Contact Person Public Query

Name	Dr Balu kolar
Designation	Manager-Product developement

Affiliation	INDUS VIVA HEALTH SCIENCES PVT.LTD
Address	INDUS VIVA HEALTH SCIENCES PVT.LTD Nandi Durga Rd, Jayamahal Extension, Benson Town, Bengaluru, Karnataka 560046 Bangalore KARNATAKA 560046 India
Phone	9902557065
Fax	
Email	dr.balu@indusviva.com

Source of Monetary or Material Support

IndusViva HealthSciences Pvt. Ltd., Nandi Durga Rd, Jayamahal Extension, Benson Town, Bengaluru, Karnataka 560046

Primary Sponsor

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

India

Sites of Study

No of Sites = **1**

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

No of Ethics Committees= **1**

Name of Committee	Approval Status
Shettys Hospital -Ethics committee	Approved

Regulatory Clearance Status from DCGI

Status
Not Applicable

Health Condition / Problems Studied

Health Type	Condition
Healthy Human Volunteers	Over weight

Patients	**(1) ICD-10 Condition:**E663||Overweight. **Ayurveda Condition:** ATISTHAULYAM (KEVALA-KAPHA),

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

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

ExclusionCriteria

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 Study Completion (India)	15/01/2022
Date of First Enrollment (Global)	Date Missing
Date of Study Completion (Global)	Date Missing
Estimated Duration of Trial	**Years=**"0" **Months=**"6" **Days=**"0"
Recruitment Status of Trial (Global) Modification(s)	Not Applicable
Recruitment Status of Trial (India)	Completed
Publication Details	NIL
Individual Participant Data (IPD) Sharing Statement	**Will individual participant data (IPD) be shared publicly (including data dictionaries)?** **Response** - NO
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

Close

FULL DETAILS (Read-only) -> Click Here to Create PDF for Current Dataset of Trial

CTRI Number	**CTRI/2021/09/036551** [Registered on: 16/09/2021] **Trial Registered Prospectively**
Last Modified On:	17/03/2022
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Ayurveda
Study Design	Randomized, Parallel Group, Placebo Controlled Trial
Public Title of Study	Clinical trial on skin health
Scientific Title of Study	A randomized, double blind, parallel assignment, placebo-controlled, two arm study to evaluate the safety and efficacy of iGlow (poly herbal preparation) on overall skin health among healthy adult volunteers
Trial Acronym	

Secondary IDs if Any

Secondary ID	Identifier
RRS/CL/IGL/SH/2020 Version 1.0 dated 20th March 2020	Protocol Number

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

Name	Dr Ashok Godavarthi
Designation	C E O
Affiliation	Radiant Research Services Pvt. Ltd
Address	Plot No:99/A, 8th Main Road, III Phase, Peenya Industrial Area, Bengaluru, 560058, Karnataka, India Bangalore KARNATAKA 560058 India
Phone	9880999297
Fax	
Email	ashok@radiantresearch.in

Details of Contact Person Scientific Query

Name	Dr Ashok Godavarthi
Designation	C E O
Affiliation	Radiant Research Services Pvt. Ltd
Address	Plot No:99/A, 8th Main Road, III Phase, Peenya Industrial Area, Bengaluru, 560058, Karnataka, India Bangalore KARNATAKA 560058 India
Phone	9880999297
Fax	
Email	ashok@radiantresearch.in

Details of Contact Person Public Query

Name	MrShariq Afsar Thandu
Designation	Senior research scientist
Affiliation	IndusViva HeathSciences Pvt.Ltd

Address	Nandi Durga Rd, Jayamahal Extension, Benson Town, Bengaluru, Karnataka Bangalore KARNATAKA 560046 India
Phone	7892470754
Fax	
Email	research@ingexbio.com

Source of Monetary or Material Support

IndusViva HealthSciences Pvt. Ltd., Nandi Durga Rd, Jayamahal Extension, Benson Town, Bengaluru, Karnataka 560046

Primary Sponsor

Name	IndusViva HealthSciences Pvt Ltd
Address	Nandi Durga Rd, Jayamahal Extension, Benson Town, Bengaluru, Karnataka 560046
Type of Sponsor	Other [Ayurveda and wellness]

Details of Secondary Sponsor

Name	Address
NIL	NIL

Countries of Recruitment

India

Sites of Study

No of Sites = **1**

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
DrMadan Mohan N T	Sri Venkateshwara Hospitals	First Floor OPD Room number 2 No 27, 29th Main Road,Rashtra Kuvempu Nagara, BTM 2nd stage, BTM layout Bangalore KARNATAKA	9845074316 drmadan1969@gmail.com

Details of Ethics Committee

No of Ethics Committees= **1**

Name of Committee	Approval Status
Sri Venkateshwara Hospitals Ethics commitee	Approved

Regulatory Clearance Status from DCGI

Status
Not Applicable

Health Condition / Problems Studied

Health Type	Condition
Healthy Human Volunteers	Skin health

Intervention /

Type	Name	Details

Comparator Agent	Intervention	I Glow Sachet	Dosage form: Sachet Dose:30 ml Duration: twice a day for 90 days. preferable 15 minutes after lunch and dinner daily.
	Comparator Agent	Placebo Sachet	Dosage form: Sachet Dose:30 ml Duration: twice a day for 90 days. preferable 15 minutes after lunch and dinner daily

Inclusion Criteria	**Age From**	18.00 Year(s)
	Age To	55.00 Year(s)
	Gender	Both
	Details	1. Subjects in generally good health 2. Subjects age group 18 - 55 years 3. Subjects willing to follow the suggested diet plan. 4. Subjects willing to give a written informed consent and come for a regular follow up 5. Subject willing to abide by and comply with the study protocol 6. Subject has not participated in a similar investigation in the past four weeks. 7. Subjects having visible fine lines and wrinkles in periorbital area (Crow’s feet), nasolabial areas, forehead , and perioral regions of the face 8. Subjects having mild to moderate naso-labial folds 9. Subjects having apparent mild to moderate crow’s feet in unanimated face 10. Subjects who have not under gone any facial anti-ageing procedures (e.g.Botulinum dermal filler injections, laser resurfacing) in the past 3 months. 11. Subject should be willing to abstain from spa treatments/facials during the study period

ExclusionCriteria	**Details**	1. A known history or present condition of allergic response to any cosmetic products. 2. Subjects having severe photo-aging. 3. Subject having skin diseases (e.g. moderate to severe acne vulgaris face or nodulocystic acne, psoriasis, active atopic dermatitis, melasma, lichen planus pigmentosus/ Achy dermatosis, pigmented contact dermatitis or other cutaneous manifestations), which will interfere with the test readings. 4. Subjects on oral medications (e.g. steroids, anti-oxidant) or any skin supplement for skin care which will compromise the study. 5. Systemic treatment which may modify the cutaneous state on the day of inclusion or in the previous 30 days, including retinoid therapy. 6. Subjects not willing to discontinue other topical anti-ageing, anti-wrinkle facial products. 7. Subjects who are pregnant, lactating or nursing. 8. Hypersensitivity to any component of the tested products. 9. History of intense sun exposure. 10. Chronic illness which may influence the cutaneous state. 11. Subject participating in any other cosmetic or therapeutic trial. 12. Any underlying uncontrolled medical illness including diabetes mellitus, hypertension, liver disease or history of alcoholism, HIV, hepatitis, or any other serious medical illness

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 iGlow through, a. Measuring vitals b. Laboratory Parameters Hematology, Biochemistry, liver profile, Kidney profile, Lipid Profile, Urine analysis, FBS & ECG at Screening (- 7 day) and end of the Study (90 day). / Day 0 Day 45 and Day 90
Secondary Outcome	**Outcome** / **TimePoints** 2. Secondary Measurement will be to assess the efficacy of iGlow through, • Dermatologist's visual assessment.ii. Instrumental measurements- Visioscan (Skin topography), • Cutometer (Elasticity), Corneometer (Skin Hydration) & • Chromameter (Skin lighting). • iii. Subject's self-assessment. • iv. Biomarker measurement • a. Procollagen • b. Serum Collagen levels • c. Elastin • d. HAS-1 (Hyaluronic Acid Synthase-1) • e. CoQ10 • f. TEWL ((Transepidermal water loss) • g. Skin elasticity / Day 0 Day 45 and Day 90
Target Sample Size	**Total Sample Size=**"90" **Sample Size from India=**"90" **Final Enrollment numbers achieved (Total)=** "90" **Final Enrollment numbers achieved (India)=**"90"
Phase of Trial	Phase 3/ Phase 4
Date of First Enrollment (India)	16/09/2021
Date of Study Completion (India)	09/03/2022
Date of First Enrollment (Global)	Date Missing
Date of Study Completion (Global)	Date Missing
Estimated Duration of Trial	**Years=**"1" **Months=**"0" **Days=**"0"
Recruitment Status of Trial (Global) Modification(s)	Not Applicable
Recruitment	Completed

Status of Trial (India)	
Publication Details	NIL
Individual Participant Data (IPD) Sharing Statement	**Will individual participant data (IPD) be shared publicly (including data dictionaries)?** **Response** - NO
Brief Summary	iGlow is a natural product based on traditional Ayurvedic principles. It provides powerful anti-aging support that strengthens the collagen of the skin & repairs it at the cellular level. iGlow is a new compound infused with Indian source of plant species extracts of Kadali (Musa paradisiaca), Karkati (Carica papaya), Narangi (Citrus sinensis), Kumari (Aloe barbadensis), Seva (Pyrus malus), Asana (Pterocarpus marsupium), Draksha (Vitis vinifera), Palakya (Spinacea olarocea), Kesara (Crocus sativus) style and stigma, Triphala, Liq. Of Narikela (Cocus nucifera) End., Shodhita yashada. iGlow keeps your skin hydrated. iGlow with essential protein boost your collagen and elastin. iGlow consumption can increase skin elasticity and helps in skin repair process, thus encouraging your body to form new collagen. It also helps to reduce the effects of aging, such as by adding moisture to the skin .

Close

FULL DETAILS (Read-only) -> Click Here to Create PDF for Current Dataset of Trial

CTRI Number	**CTRI/2020/09/027807** [Registered on: 15/09/2020] **Trial Registered Prospectively**
Last Modified On:	17/03/2022
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Ayurveda
Study Design	Randomized, Parallel Group Trial
Public Title of Study	Ayurveda product clinical trial on overweight subjects
Scientific Title of Study	A randomized, multi-center, double blind, parallel assignment, placebo- controlled, two arm study to assess safety and efficacy of iSlim flat tummies for weight management in adult male and/or female obese or overweight subjects.
Trial Acronym	

Secondary IDs if Any

Secondary ID	Identifier
RRS/CL/ISL/OW/2020 Version Number 1.0 dated 26 Mar 2020	Protocol Number

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

Name	Dr Ashok Godavarthi
Designation	C.E.O
Affiliation	Radiant Research Services Pvt Ltd
Address	RADIANT RESEARCH SERVICES PVT. LTD. Plot No:99 A, 8th Main Road, III Phase, Peenya Industrial Area, Bengaluru, 560058, Karnataka, India. Bangalore KARNATAKA 560058 India
Phone	9880999297
Fax	
Email	ashok@radiantresearch.in

Details of Contact Person Scientific Query

Name	Dr Ashok Godavarthi
Designation	C.E.O
Affiliation	Radiant Research Services Pvt Ltd
Address	RADIANT RESEARCH SERVICES PVT. LTD. Plot No:99 A, 8th Main Road, III Phase, Peenya Industrial Area, Bengaluru, 560058, Karnataka, India. KARNATAKA 560058 India
Phone	9880999297
Fax	
Email	ashok@radiantresearch.in

Details of Contact Person Public Query

Name	Dr Balu kolar
Designation	Manager-Product developement
Affiliation	IndusViva HealthSciences Pvt. Ltd.

Address	IndusViva HealthSciences Pvt. Ltd. Nandi Durga Rd, Jayamahal Extension, Benson Town, Bengaluru, Karnataka 560046 Bangalore KARNATAKA 560046 India
Phone	9902557065
Fax	
Email	dr.balu@indusviva.com

Source of Monetary or Material Support

IndusViva HealthSciences Pvt. Ltd., Nandi Durga Rd, Jayamahal Extension, Benson Town, Bengaluru, Karnataka 560046

Primary Sponsor

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

India

Sites of Study
Modification(s)

No of Sites = **2**

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr Chikkalingaiah Siddegowda	Medstar Speciality Hospital	No. 641/17/1/3, Kodigehalli Main Road Ground floor Department of general medicine Room Number 2,Sahakarnagar Post, Bangalore, Karnataka-560092, India Bangalore KARNATAKA	9844004187 drchikkalingaiahmedstar@gmail.com
DrK Sunil Naik	Rajiv Gandhi Institute of Medical Sciences	Dept. of general medicine, Room no 15,First floor, Shanti NagarColony, Balaga, Srikakulam,Andhra Pradesh 532001 Srikakulam Srikakulam ANDHRA PRADESH	919440828299 rimsresearch@gmail.com

Details of Ethics Committee
Modification(s)

No of Ethics Committees= **2**

Name of Committee	Approval

	Status
Institutional Ethics Committe Medical college & Government General Hospital - Government	Approved
Medstar Speciality Hospital Ethics Committee	Approved

Regulatory Clearance Status from DCGI

Status
Not Applicable

Health Condition / Problems Studied

Health Type	Condition
Healthy Human Volunteers	Weight management

Intervention / Comparator Agent

Type	Name	Details
Intervention	iSlim Herbal formulation	Dose: once daily by skipping the lunch Dosage form: bar formulation Route of administration: Orally Duration: 90 days
Comparator Agent	placebo	Dose: once daily by skipping the lunch Dosage form: bar formulation Route of administration: Orally Duration: 90 days

Inclusion Criteria

Age From	18.00 Year(s)
Age To	55.00 Year(s)
Gender	Both
Details	1.Adult male and non-pregnant females aged 18 to 55 years 2.BMI ≥ 25 kg/m2 to 40 kg/m2 with one or more of the metabolic risk factors (waist circumference ≥80 cm, fasting glucose ≥100 mg/dL, BP ≥130/85 mmHg, HDL-cholesterol <50 mg/dL OR controlled diabetes, hypertension, dyslipidemia with medications) 3.Able to comply with all required study procedures and schedule. 4.Able to comply and willing to follow the prescribed diet plan. 5.Willing and able to give written informed consent. 6.Subjects who agree to stop from using supplements during the study duration time 7.Subjects willing to refrain from any obesity treatment 8.Subjects willing to follow the suggested diet plan

ExclusionCriteria

Details	1. Participants with uncontrolled hypertension (systolic blood pressure (SBP) >180 mmHg, or diastolic blood pressure (DBP) >120 mmHg) 2. Participants with hepatic disease (aspartate aminotransferase (AST)/alanine aminotransferase (ALT) >3 x institutional upper limit of normal) or renal disease (serum creatinine >2.0 mg/dL) 3. Participants with significant cardiovascular disease or stroke 4. Participants with history of seizures 5. Endocrine disease such as hypothyroidism or Cushing syndrome 6. History or existence of neurological or psychological disease (schizophrenia, epilepsy, alcoholism, drug addiction, anorexia, bulimia and so on) 7. Use of medication within the past 3 months that could have an effect on weight (appetite suppressant, laxative, oral steroid, thyroid hormone,

	amphetamine, cyproheptadine, phenothiazine or medication having an effect on absorption, metabolism and excretion). 8. A know history or present condition of allergic response to any pharmaceutical products and supplements. 9. History of weight reduction surgery, bariatric surgery and so on 10. Weight reduction > 10% within the past 6 months 11. Women in child bearing age unable to practice any form of contraception 12. Participants on herbal supplements/any other wellness product 13. History of alcohol, tobacco, substance or drug abuse 14. Subject who has participated in a clinical study within the last 30 days prior to entering this study. 15.Participants with hypersensitivity to any of the ingredients of the study products. 16. Refusing consent or physician uncomfortable with patient compliance to treatments or follow up.
Method of Generating Random Sequence	Computer generated randomization
Method of Concealment	Case Record Numbers
Blinding/Masking	Double Blind Double Dummy
Primary Outcome	**Outcome** / **TimePoints** 1.Primary Measurement will be the safety and tolerability of iSlim flat tummies through, 2.Laboratory Parameters Hematology, Biochemistry, liver profile, Kidney profile, Lipid Profile, Urine analysis, Fasting blood glucose, & ECG at Screening (-0 day) and end of the Study (90 day). — Day 0 and Day 90
Secondary Outcome	**Outcome** / **TimePoints** 1.Body Weight/BMI: The difference in mean percent loss of baseline body weight. OR, the proportion of subjects who lose at least 5 percent of baseline body weight. 2.HbA1c Activity 3.Blood Pressure 4.Fasting Blood Glucose and Serum Insulin 5.Lipid Profile 6.Waist Circumference 7.Inflammatory Biomarker: ESR & hsCRP 8.Serum biomarkers: Leptin and Ediponectin 9.Appetite measure: Simplified Nutritional Appetite Questionnaire (SNAQ) 10.Subject Photographs (day 0 and day 90) — Day 0,Day 45 and Day 90
Target Sample Size	**Total Sample Size=**"70" **Sample Size from India=**"70" **Final Enrollment numbers achieved (Total)=** "70" **Final Enrollment numbers achieved (India)=**"70"
Phase of Trial	Phase 3/ Phase 4
Date of First Enrollment (India)	18/09/2020
Date of Study	30/12/2021

Completion (India)	
Date of First Enrollment (Global)	Date Missing
Date of Study Completion (Global)	Date Missing
Estimated Duration of Trial	**Years=**"1" **Months=**"0" **Days=**"0"
Recruitment Status of Trial (Global) Modification(s)	Not Applicable
Recruitment Status of Trial (India)	Completed
Publication Details	NIL
Individual Participant Data (IPD) Sharing Statement	**Will individual participant data (IPD) be shared publicly (including data dictionaries)?** **Response** - NO
Brief Summary	iSlim flat tummies is a bar formulation, with many kinds of natural herbal ingredients packed by a synergistic composition have shown to fight cravings and boost fat burning and weight management. iSlim flat tummies is a proprietary bar formula designed effectively with major specialized botanicals like *Salacia reticulata, Coleus forskohlii and Sesamum indicum.* It also contains vitamins and minerals. iSlim flat tummies an Ayurveda herbal supplements offers a comprehensive weight-management support. This can help you to achieve a balance weight, but results no side effects. iSlim flat tummies results in giving more stamina, a better-functioning body and youthful appearance. It is enriched with time tested herbal extracts and naturally derived plant proteins that improve immune function, boosts metabolism in body, act as appetite suppressant, fat blocker, hepatoprotective and supports healthy weight loss while it effectively flattens your tummies. iSlim flat tummies is a best weight management bar, enchanting with mouth-watering taste.

Close