Clinical Trial Details (PDF Generation Date :- Wed, 07 Jun 2023 16:24:39 GMT)

CTRI Number	CTRI/2022/08/044808 [Registered on: 22/08/2022] - **Trial Registered Prospectively**
Last Modified On	23/03/2023
Post Graduate Thesis	No
Type of Trial	Observational
Type of Study	Cohort Study
Study Design	Other
Public Title of Study	Development of an Algorithm for Ultrahuman Health Platform
Scientific Title of Study	Development of an Algorithm to Assess Metabolic Health of Non-diabetic and Pre-diabetic South-Asian Population Using Continuous Glucose Monitoring Systems and Ultrahuman Health Platform

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	Suresh Kumar Karri
Designation	Sr. Project Manager
Affiliation	Triomics Healthcare Pvt Ltd
Address	Level 5, Green Boulevard, Block C, Sector 62 Noida Uttar Pradesh 201 301 India Gautam Buddha Nagar UTTAR PRADESH 201310 India
Phone	9739798272
Fax	
Email	suresh.karri@triomics.in

Details Contact Person (Scientific Query)

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Name	Suresh Kumar Karri
Designation	Sr. Project Manager
Affiliation	Triomics Healthcare Pvt Ltd
Address	Level 5, Green Boulevard, Block C, Sector 62 Noida Uttar Pradesh 201 301 India Gautam Buddha Nagar UTTAR PRADESH 201310 India
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Source of Monetary or Material Support

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> Ultrahuman Healthcare Pvt Ltd 45/3, Residency Rd, Shanthala Nagar, Ashok Nagar, Bengaluru, Karnataka 560025

Primary Sponsor

Primary Sponsor Details	
Name	Ultrahuman Healthcare Pvt Ltd
Address	1st Floor Gopala Krishna Complex, #45/3 Residency Road, Bangalore, Karnataka, India - 560025
Type of Sponsor	Other [A preventive healthcare technology]

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
Dr R P Rajesh	Aadhavvan Diabetes & Research Centre	No.3, 5th Street, Eswar Nagar, Kodambakkam, Chennai - 600024 Chennai TAMIL NADU	9629394222 doctorrpr@gmail.com
Dr Prabhat Ranjan Sinha	Aakash Healthcare Private Limited Hospital	Plot Road No. 201, Sector-3, Dwarka, New Delhi -110075 South West DELHI	9811709628 drprabhatsinha@yahoo.com
Dr Neeta Deshpande	Belgaum Diabetes Centre	Ground and second floor, maruti street, Belgaum- 590001 Belgaum KARNATAKA	9880271313 neetarohit@gmail.com
Dr Banshi Saboo	Diacare Research	1,2 Gandhi Park, near nehrunagar, Ambawadi, Ahmedabad- 380015 Ahmadabad GUJARAT	8375079880 banshisaboo@hotmail.com
Dr Suresh S M	Dr. Suresh Diacare	No 723B, 11th Main Rd, 3rd Block, Rajajinag, Bengaluru 560010 Bangalore KARNATAKA	9844011862 sureshhospital@gmail.com
Dr BVSN Raju	Induss Hospital	Opposite Kothapet Fruit Market Kothapet, Sri Sai Shivani Complex, HUDA Complex, Saroornagar 500035 Hyderabad TELANGANA	9440383778 vsnarayanraju10@gmail.com
Dr Sriharee Kulkarni	Kulkarnis Medzone	Kulkarrni Medzone, G D Naidu Hall, Mohan Matrix,, 450, 12th Cross Rd, near Vidya Bharathi School,	9480427359 drsriharee@gmail.com

		Mahalakshmipuram Bangalore KARNATAKA	
Dr Pankaj Aneja	Naveda Healthcare Center	A-1/81, Sector - 8, Rohini, Delhi 110085 North West DELHI	9811117266 drpankajaneja@gmail.com
Dr Hamsraj Alva	Vinaya Hospital and Research Centre (a unit of KIMS)	Karangalpady, Mangaluru-575003 Dakshina Kannada KARNATAKA	9343562622 hansalva2001@yahoo.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Aakash Healthcare Private Limited	Approved	11/08/2022	No
Bangalore Ethics Committee	Approved	03/10/2022	Yes
Bangalore Ethics Committee	Approved	26/09/2022	Yes
Diabetes centre ethics committee	Approved	12/08/2022	No
Ethics committee Vinaya Hospital	Approved	30/07/2022	No
Independent ethics committee	Approved	02/08/2022	Yes
Independent ethics committee - Universal Ethics Committee	Approved	08/08/2022	Yes
Induss Hospital Institutional Ethics Committee	Approved	14/10/2022	Yes
Shrey hospital Instituitional ethics committee	Approved	12/08/2022	No

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Healthy Human Volunteers	Non-diabetic and prediabetic participants.

Intervention / Comparator Agent

Type	Name	Details

Inclusion Criteria

Inclusion Criteria	
Age From	25.00 Year(s)
Age To	50.00 Year(s)
Gender	Both
Details	General inclusion criteria for healthy and prediabetic population: Subjects within the age group of 25-50 years. Subjects willing to participate in the study. BMI within 20 – 30 kg per m2 Willing to comply to the advised use of CGM, activity tracker, CGM reader and the UH Application. Inclusion criteria for healthy population: Fasting blood glucose level at screening 79-99 mg/dl HbA1c range 4.0-5.6 percentage 2-hour plasma glucose during 75-g OGTT below 140 mg/dL (less than 7.8 mmol/L) Inclusion criteria for prediabetic population: Fasting blood glucose level at screening 100-125 mg/dl OR

	HbA1c range 5.7-6.4 percentage OR 2-hour plasma glucose during 75-g OGTT 140–199 mg/dL (7.8–11.0 mmol/L)

Exclusion Criteria

Exclusion Criteria	
Details	History of acute or subacute infection in the last three months. History of chronic illnesses and autoimmune conditions. Subjects on antimicrobial drug agents, including antibiotics, antivirals, or antifungals Subjects pre-diagnosed with Type 1 Diabetes Subjects pre-diagnosed with Type 2 Diabetes Mellitus according to the ADA (American Diabetes Association) criteria. Subjects with anemia [less than male 13 grams per dL and females less than 12 grams per dL] Documented known medical history of any impaired renal and liver function. Subjects diagnosed with cardiac disease, including angina, heart failure, arrhythmias, valvular heart disease, or congenital heart disease. Subjects with regular alcohol consumption of more than eight drinks per week and 15 drinks per week in women and men, respectively. Enrolment in any kind of weight reduction program in the last six months Unexplained intentional or unintentional weight loss of more than 10 percent of average weight in the previous six months Subjects currently on diet plans such as keto, low carb and intermittent fasting. Pregnant and lactating females Out of range results in any of the screening tests carried out for blood glucose measurements (FBG, HbA1c and OGTT tests)

Method of Generating Random Sequence	Not Applicable
Method of Concealment	An Open list of random numbers
Blinding/Masking	Not Applicable

Primary Outcome

Outcome	Timepoints
CGM-based glucose indices over 14 days of period Mean glucose levels described by a 24-hour profile during 2 weeks Time in glucose ranges Glycaemic variability as measured by the standard deviation, coefficient of variation, MAGE	Day 1 and Day 14

Secondary Outcome

Outcome	Timepoints
Changes in FBS from day 0 to day 15 Assessing the correlations between the biomarkers and metabolic health metrics, the key relationships to explore are: Glucose variability indices and sleep duration Glucose variability indices and stress (as measured by cortisol) Glucose variability indices and inflammation (as measured by Hs-CRP) Glucose variability indices and gut microbiome index Glucose variability indices and urine metabolites Glucose variability indices and physical activity (limited to step count and heart rate)	Day 0 and Day 14

Target Sample Size	**Total Sample Size=**100 **Sample Size from India=**100 **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	N/A
Date of First Enrollment (India)	24/08/2022
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**0 **Months=**3 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Closed to Recruitment of Participants
Publication Details	None yet
Brief Summary	In this prospective observational study, eligible subjects willing to participate in the study will be screened, and the subjects meeting the eligibility criteria will be enrolled in the study. Based on the ADA criteria of Screening and Diagnostic Tests for Prediabetes, the subjects will be assigned to either group A (healthy non-diabetic subjects) or group B (pre-diabetic subjects). After the screening of the subjects, urine, stool, and blood samples will be collected for baseline investigations. All the enrolled subjects will be provided with the CGM device and trained by the on-site staff on applying it to their arms. The CGM data-collection period will be 14 days (2 weeks). Based on GV Indices, Activity & Sleep data, the UH platform will provide Nudges related to GV Indices trend. Participants can modify their diet & activities accordingly. The glucose readings will be collected by the Abbott freestyle libre CGM device, which will be scanned with the subject’s phone and the supplied Abbott CGM reader. The daily food consumption will be logged on the UH application. The activity tracker will log

the physical activities, sleeping, and waking time. All participants will be provided with the necessary training to familiarize themselves with the App’s features and use.