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Blood pressure reduction in patients with high blood pressure (hypertension) with diet and lifestyle modification

Submission date 24/01/2022	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol
Registration date 25/04/2022	**Overall study status** Completed	[X] Statistical analysis plan [_] Results
Last Edited 25/04/2022	**Condition category** Circulatory System	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
High blood pressure (BP) is the leading cause of heart disease and early deaths worldwide. According to WHO, globally, 1.13 billion people have high BP, and it was estimated in 2015 that every 1 in 4 males and 1 in 5 females had high BP. Diet based therapy and lifestyle modifications serve as the first line of treatment for prevention as well as to control blood pressure in the early stage.
The Twin Health platform uses a Whole Body Digital Twin, powered by artificial intelligence and Internet of Things technology, to precisely understand the metabolic impairment in the patient’s body, which is unique to the patient. The platform collects data from body sensors and a mobile app to track and analyze the body's health signals in order to personalize patients' treatment.

Who can participate?
Adults above 18 years of age with hypertension.

What does the study involve?
Participants will be randomly allocated to receive treatment as usual or the Twin Precision treatment program for 2 years. Participants will be followed up 1 year later.

What are the possible benefits and risks of participating?
Possible benefits from the program include a reduction in blood pressure.
Possible risks will be monitored throughout by the patients’ caregivers and necessary steps will be taken to help keep glucose and fluid/electrolyte levels normal.

Where is the study run from?
Bangalore Diabetes Centre (India)

When is the study starting and how long is it expected to run for?
January 2022 to January 2025

Who is funding the study?
Twin health (India)

Who is the main contact?
Dr Paramesh Shamanna, drparamesh2@gmail.com

Contact information

Type(s)
Principal investigator

Contact name
Dr Paramesh Shamanna

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Additional identifiers

Protocol serial number
TPT- 4/2021

Study information

Scientific Title
Efficacy and safety of Twin Precision treatment in patients with hypertension - a multicentre, open-label, randomised controlled trial

Acronym
TPT

Study objectives
To compare the mean change in systolic and diastolic 24 hr blood pressure ambulatory from baseline to 1 year between the 2 groups.
To compare the mean change in systolic and diastolic blood pressure clinic based from baseline to 1 year between the 2 groups.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/01/2022, Medisys Clinisearch Ethical Review Board (Medisys Clinisearch India Private Limited,
Bangalore Diabetes Center, No. 426, 4th Cross, 2nd Block, Kalyan Nagar, Bangalore - 560043, Karnataka, India; +91 80 2542 1333; bhargavicrc@gmail.com), ref: none provided

Primary study design
Interventional

Study design
Multicentric open-label randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Hypertension

Interventions
Patients randomized to the intervention group will follow the medicine, exercise, sleep and nutritional syntax of the Twin Precision Treatment program.

Group 1 Standard care arm
Lifestyle modifications and medications as per current guidelines (ISH).

Group 2 Intervention arm (Twin Precision treatment)
The platform collects data from body sensors and a mobile app to track and analyze the body's health signals to personalize patients' treatment.
Individualized medicine, exercise, sleep and nutritional syntax of the Twin Precision Treatment program guided by artificial intelligence will be administered.

Duration of intervention 2 years
Duration of follow up 1 year

Randomisation
Patients will be randomized into either the standard care arm or the intervention arm using central randomisation in a ratio of 1:2 (standard arm: intervention arm). Block randomisation of variable block size or in other words, random permuted blocks will be used where the size of the next block will be randomly chosen from the available block sizes. Since the randomization ratio is 1:2, the random permuted blocks of sizes 3 or multiples of 3 will be selected. Random numbers and sequences will be generated through an online tool which is given by sealed envelope.com. Since block randomization is done by varying block sizes, the permutation of sequences may not be identified to reduce the bias.

Intervention Type
Behavioural

Primary outcome(s)
1. Blood pressure as measured by ambulatory blood pressure monitoring at baseline and the end of 1 year
2. Blood pressure as measured in the clinic at baseline and the end of 1 year

Key secondary outcome(s)
1. Blood pressure (clinical and ambulatory blood pressure) at baseline, 6 months, and 2 years
2. Adequate control of blood pressure as measured by ambulatory blood pressure monitoring at 1 year and 2 years
Criteria for adequate control of blood pressure is:
In <65 years < 130/80 mm Hg
In 65 and above < 140/90 mm Hg
3. Number of antihypertensive medications at 6 months, 1 year and 2 years measured using patient records

Completion date
14/01/2025

Eligibility

Key inclusion criteria
1. Patients with a diagnosis of primary hypertension (either adequately controlled or inadequately controlled with blood pressure ≤180/110 mm Hg); both treatment-naive & on treatment (includes monotherapy or multiple drugs)
2. Aged 18 years and above
3. Willing to follow study specific activities and able to handle smartphone

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Uncontrolled hypertension (>180/110 mm of Hg) or history of hypertensive emergency requiring admission
2. Hypertension due to secondary causes
3. History of Diabetes mellitus (when either of the following criteria is met: on medications to control blood sugar or FBS >126 mg/dl; RBS >200 mg/dl; HbA1c ≥6.5)
4. Symptomatic heart failure or EF <40%
5. Chronic kidney disease (eGFR less than 60 ml/min/1.73 m^2) or history of any major renal anomalies like unilateral kidney, polycystic kidney
6. Any major cardiovascular event in the last 6 months (such as MI, stroke, TIA)
7. Hypertensive Retinopathy (grade 3 and above)
8. Weight loss more than 5% in 3 months
9. Arm circumference too large or small to allow accurate BP measurement with available devices

10. Special dietary requirements, or medications that would affect blood pressure (other than antihypertensive drugs) or nutrient metabolism
11. Unwilling or inability to modify current diet
12. Hypercalcemia (>10.5 mg/dl) and Hyperkalemia.(>5.5 mmol/l)
13. Known Malignant cases <5 years
14. Anemia (Hb <8 gm)
15. Major Gastrointestinal diseases such as Inflammatory bowel disease, irritable bowel syndrome that can interfere with dietary intervention
16. Use of contraindicated drugs such as antacids of magnesium, calcium, steroids, lithium, anti-migraine drugs, phenytoin, anti-psychotics (SSRI, SNRI, and TCA), immuno-modulators, any narcotic drugs, and oral contraceptives.
17. Having received any investigational drug or device within 30 days prior to entry into the study
18. Poor compliance during screening or run in.
19. Autoimmune disorders and Connective tissue disorders
20. Total bilirubin of >2 mg/dL or aspartate aminotransferase (AST) and alanine aminotransferase (ALT) 5 times the upper limit of normal range
21. Pregnant or planning to conceive in the next 3 years or breastfeeding
22. Psychiatric illness such as psychosis, manic depressive illness, alcohol or drug dependence.
23. Consumption of >14 alcoholic beverages per week (for women) and >21 for men
24. Any other condition or illness that the investigator feels would make the patient ineligible or make the patient difficult to participate in the study

Date of first enrolment
01/05/2022

Date of final enrolment
01/09/2022

Locations

Countries of recruitment
India

Study participating centre
Bangalore Diabetes Centre
426, CMR Main Rd
HRBR Layout 2nd Block
Kalyan Nagar
Bengaluru
India
560043

Study participating centre
Chandana clinic
No.13/4, 7th Main Road,Bhuvaneshwari Nagar, Hesaraghatta Main Road Bangalore - 560057, Karnataka, India
Bangalore

India
560057

Sponsor information

Organisation
Twin Health

Funder(s)

Funder type
Industry

Funder Name
Twin Health

Results and Publications

Individual participant data (IPD) sharing plan
All of the individual participant data collected during the trial, after de-identification data will be shared
Name- Dr Paramesh Shamanna
Email- paramesh@twinhealth.com
Data type- Digital format in Twin ICAP
Data availability - 3 years from the start of Trial
Data accessibility: Data will be accessible in digital format after the consent is obtained from participants and participant identity will be anonymised.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.1.1	09/03/2022	20/04/2022	No	No
Statistical Analysis Plan			20/04/2022	No	No