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Effect of the Twin Precision diet intervention on hypertension

Submission date	**Recruitment status**	[X] Prospectively registered
16/01/2021	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
13/05/2021	Ongoing	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
13/12/2022	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Elevated blood pressure arises from a combination of genetic and environmental risk factors. Some of the risk factors include high salt intake, low potassium intake, sedentary lifestyle, obesity, unhealthy diet and alcohol consumption. Also, patients with hypertension exhibit insulin resistance and hypertriglyceridemia compared to normotensive controls. Nutrition based therapy and lifestyle modifications serve as the first line of treatment for prevention as well as to control blood pressure in stage 1 hypertension. Dietary modifications have been widely considered an important step in the lifestyle modification strategy for prevention of hypertension.

The Twin Precision Treatment attempts to improve blood pressure control by measuring and treating the dysfunctional metabolism in the hypertensive patient. Using Digital Twin technology powered by artificial intelligence (AI) and Internet of Things (IoT) technologies, the Whole-Body Digital Twin Platform captures data on up to 174 health markers, up to 3000 daily data points to provide precision nutrition guidance to the patient that precisely balances 87 essential nutrient factors to optimize the metabolic functioning of the patient. Additionally, the Whole-Body Digital Twin platform also captures daily physical activity, sleep data and provides precision guidance on activity and sleep for the patient to follow.

Who can participate?
Participants on treatment for hypertension of either gender between 18 to 70 years can participate in this trial.

What does the study involve?
Participants will be randomised into either standard care arm (standard care medications for hypertension) or intervention arm (standard care plus twin precision treatment for diet modification) for 1 year. Follow up will continue for 2 years.

What are the possible benefits and risks of participating?
Participants in the intervention arm is expected to have normalization of blood pressure along with reduction in the number of anti-hypertensive medications. There is a rare chance for either lowering of blood pressure (hypotension) or increase in blood pressure (hypertension)

Participants in the standard treatment arm will benefit by regular monitoring of blood pressure along with investigations for hypertension related complications.

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

When is the study starting and how long is it expected to run for?
November 2020 to December 2027

Who is funding the study?
Twin Health Pvt. Ltd. (India)

Who is the main contact?
Dr Paramesh Shamanna, paramesh@twinhealth.com

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
TPT- 2/2020

Study information

Scientific Title
Efficacy and safety of Twin Precision treatment protocol on hypertension- an open label randomised controlled trial

Study objectives
Twin Precision based diet is effective in improving blood pressure and reducing requirement for anti-hypertensive medications

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/12/2020, Medisys Clinisearch Ethical review board (No. 426, 4th cross, 2nd block, Kalyan Nagar, Bangalore, 560043, Karnataka, India; +91 (0)80 25902546; bhargavicrc@gmail.com), ref: MCERB/2020/06

Study design
Open label randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
High blood pressure

Interventions
Twin Precision treatment involves providing a personalising diet based on glycaemic excursions along with care of macro and micronutrients.

The first phase will be a pilot study to check for the feasibility and plan the required sample size.
2 forms of diet intervention will be tried based on the net carbs utilised.
One arm will receive Twin Precision diet with net carbs less than 50.
The other arm in addition to Twin Precision diet net carbs 50 to 100 will be allowed
The intervention will be for a period of 3 months

Patients in the pilot study will be given an option to continue in the main study.

The second phase will be the main trial with 2 groups.
Group A will receive standard medications for hypertension.

Group B will receive Twin Precision Nutrition along with the standard of care medications for hypertension.
Intervention period: 1 year
Follow up for additional 2 years (minimum of 1 year)

Intervention Type
Behavioural

Primary outcome(s)
1. Blood pressure as measured by ambulatory blood pressure monitoring at baseline and 3 months
2. Blood pressure as measured in the clinic (sphygmomanometer) at baseline and 3 months

Key secondary outcome(s))
1. Blood pressure measured by ambulatory blood pressure monitoring and in the clinic (sphygmomanometer) at 6 months and 1 year
2. Requirement of antihypertensive medications (at 3 months, 6 months and 1 year) measured using patient records
3. Metabolic parameters at baseline, 3 months, 6 months and 1 year:
3.1. Height (cm), Weight (kg), BMI (kg/m^2), waist circumference (cm), visceral fat (MRI)
3.2. Lipid profile lipoprotein, apolipoprotein, insulin resistance (fasting blood sugar and insulin level), thyroid profile, testosterone, measured by a blood test
4. Inflammatory markers. Complete blood count with ESR, hsCRP, uric acid at baseline, 3 months, 6 months and 1 year.
5. Hypertension mediated organ damage (Brain, cardiac, kidney and eye) assessment:
5.1. Cardiac parameters. ECG, Echocardiography, carotid Intimal Media Thickness (cIMT), NT pro BNP. Baseline, 3 months, 6 months and 1 year
5.2. Eye assessment. Fundus examination (for hypertensive retinopathy). baseline, 1 year and 2 years
5.3. Neurological assessment using Montreal Cognitive assessment (in patients 60 years and above) assessed at baseline and 1 year.
5.4. Renal assessment (Blood urea, serum creatinine, eGFR and albumin creatinine ratio) Baseline, 3 months, 6 months and 1 year
6. Major adverse cardiac outcomes such as occurrence of MI, stroke if any throughout the study period measured using patient records
7. Safety outcomes (adverse effects, abnormal changes in blood investigations, frequency of uncontrolled hypertension, hospital admissions due to uncontrolled blood pressure etc) 1 year measured using patient records
8. Improvement in quality of life. SF-36. Baseline, 3 months, 6 months and 1 year
9. Treatment satisfaction. Treatment satisfaction questionnaire. Baseline, 3 months, 6 months and 1 year
10. Stress assessment using the Perceived Stress Questionnaire Baseline, 3 months, 6 months and 1 year
11. Exploratory biomarkers: Markers of endothelial function (Endothelin, VCAM) and antioxidant stress biomarkers (cortisol, malondialdehyde, nitric oxide and glutathione) measured at baseline, 3 months, 6 months and 1 year
12. Other Blood parameters: ferritin, vitamin B12, folic acid, other vitamins and minerals, electrolytes, testosterone and estradiol. Blood test. Baseline, 3 months, 6 months and 1 year

Completion date
31/12/2027

Eligibility

Key inclusion criteria
1. Patients between 18 to 70 years of age
2. On treatment for hypertension (monotherapy or multiple drugs)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
312

Key exclusion criteria
1. Uncontrolled hypertension (>180/110 mm/Hg) or history of hypertensive emergency requiring admission
2. Hypertension due to secondary causes
3. Diabetes mellitus
4. Heart failure with EF <45%
5. eGFR less than 60 ml/min/1.73 m²
6. Any major cardiovascular event in the last 12 months (such as MI, stroke, TIA)

Date of first enrolment
15/04/2022

Date of final enrolment
31/12/2023

Locations

Countries of recruitment
India

Study participating centre
Bangalore Diabetes Centre
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Bangalore
India
560043

Sponsor information

Organisation
Twin Health

Funder(s)

Funder type
Industry

Funder Name
Twin Health

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. Deidentified data will be archived for a period of 5 years from the time of completion of study and will be available upon request after publication of analysed results.

IPD sharing plan summary
Available on request