

PRS TEST SYSTEM

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Protocol Registration System



Protocol Registration Preview

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Example Cross-Over Study Design***

This study has been completed.

Sponsor:	PRS Training
Collaborators:	
Information provided by (Responsible Party):	, PRS Training
ClinicalTrials.gov Identifier:	

► Purpose

The objective of the study is to determine whether Hypertena has an effect on reducing systolic and diastolic blood pressure in participants diagnosed with high blood pressure.

Condition	Intervention	Phase
High Blood Pressure	Drug: Hypertena Drug: Placebo	Phase 2

Study Type: Interventional

Study Design: Treatment, Crossover Assignment, Double Blind (Subject, Investigator), Randomized, Efficacy Study

Official Title: Phase II, Randomized, Double-Blind, Cross-Over Study of Hypertena and Placebo in Participants With High Blood Pressure

Further study details as provided by , PRS Training:

Primary Outcome Measure:

- Change From Baseline in Mean Sitting Systolic Blood Pressure (SBP) at 2 Weeks [Time Frame: Baseline and 2 Weeks] [Designated as safety issue: No]

Blood pressure was assessed after the participant was in a seated position for at least 5 minutes. Blood pressure was measured with an automated measurement device 3 times at 1 to 2 minute intervals and a mean of the 3 measurements was

calculated.

- Change From Baseline in Mean Sitting Diastolic Blood Pressure (DBP) at 2 Weeks [Time Frame: Baseline and 2 Weeks] [Designated as safety issue: No]

Blood pressure was assessed after the participant was in a seated position for at least 5 minutes. Blood pressure was measured with an automated measurement device 3 times at 1 to 2 minute intervals and a mean of the 3 measurements was calculated.

Secondary Outcome Measures:

- Percentage of Participants With Response [Time Frame: 2 Weeks] [Designated as safety issue: No]

Percentage of participants achieving a mean sitting systolic blood pressure < 140 mmHg and a mean sitting diastolic blood pressure < 90 mmHg at 2 weeks (Response Rate)

Enrollment: 130

Study Start Date: May 2008

Study Completion Date: February 2009

Primary Completion Date: February 2009

Arms	Assigned Interventions
<p>Active Comparator: Hypertena, Then Placebo</p> <p>Participants first received Hypertena 20 mg tablet each morning in a fasting state for 2 weeks. After a washout period of 2 weeks, they then received Placebo tablet (matching Hypertena 20 mg tablet) in a fasting state each morning for 2 weeks.</p>	<p>Drug: Hypertena 20 mg tablet</p> <p>Drug: Placebo Hypertena-matched Placebo tablet</p>
<p>Active Comparator: Placebo, Then Hypertena</p> <p>Participants first received Placebo tablet (matching Hypertena 20 mg tablet) each morning in a fasting state for 2 weeks. After a washout period of 2 weeks, they then received Hypertena 20 mg tablet in a fasting state each morning for 2 weeks.</p>	<p>Drug: Hypertena 20 mg tablet</p> <p>Drug: Placebo Hypertena-matched Placebo tablet</p>

Enrolled patients with high blood pressure, who are being treated at a specialty clinic associated with a hospital in Springfield, IL, will be randomized to receive either Hypertena or Placebo first and then will be crossed over to receive the opposite Intervention. The study will consist of two treatment periods of 2 weeks separated by a washout period of 2 weeks.

Eligibility

Ages Eligible for Study: 18 Years and older

Genders Eligible for Study: Both

Inclusion Criteria:

- Diagnosed with high blood pressure (Stage 1 or 2 hypertension via JNC 7: Systolic blood pressure (SBP) \geq 140 mmHg and/or diastolic blood pressure (DBP) \geq 90 mmHg)
- Required to have a sufficient level of education to understand study procedures and be able to communicate with site personnel

Exclusion Criteria:

- History of kidney disease
- Diabetes
- Acute liver injury (e.g., hepatitis) or severe cirrhosis
- Pregnancy
- Breast-feeding
- Allergy to Hypertena or lactose
- History of drug or alcohol abuse
- Participation in a study of an investigational medication within the past 30 days

▶ **Contacts and Locations**

Locations

United States, Illinois

Springfield, Illinois, United States

▶ **More Information**

Responsible Party: , Information Research Specialist, PRS Training

Study ID Numbers: HBP-QA8

Health Authority: United States: Food and Drug Administration

Study Results

▶ **Participant Flow**

Recruitment Details -- *Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations:*

200 patients were screened for eligibility between May 2008 and October 2008 at a hospital-associated specialty clinic in IL.

Pre-Assignment Details -- *Significant events and approaches for the overall study following participant enrollment, but prior to group assignment:*

130 of 200 participants were randomized. Of those not randomized, 35 did not meet inclusion criteria and 35 declined to participate.

Reporting Groups

	Description
Hypertena, Then Placebo	Participants first received Hypertena 20 mg tablet each morning in a fasting state for 2 weeks. After a washout period of 2 weeks, they then received Placebo tablet (matching Hypertena 20 mg) in a fasting state each morning for 2 weeks.
Placebo, Then Hypertena	Participants first received Placebo tablet (matching Hypertena 20 mg) in a fasting state each morning for 2 weeks. After a washout period of 2 weeks, they then received Hypertena 20 mg tablet in a fasting state each morning for 2 weeks.

First Intervention (2 Weeks)

	Hypertena, Then Placebo	Placebo, Then Hypertena
STARTED	65	65
Received Intervention	65	64
COMPLETED	65	63
Not Completed	0	2
Withdrawal by Subject	0	1
Adverse Event	0	1

Washout (2 Weeks)

	Hypertena, Then Placebo	Placebo, Then Hypertena
STARTED	65	63
COMPLETED	63	62
Not Completed	2	1
Withdrawal by Subject	2	1

Second Intervention (2 Weeks)

	Hypertena, Then Placebo	Placebo, Then Hypertena
STARTED	63	62
COMPLETED	60	62
Not Completed	3	0
Adverse Event	2	0

Lost to Follow-up	1	0
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▶ Baseline Characteristics

Reporting Groups

	Description
All Study Participants	Participants who were randomized to receive either Hypertena 20 mg tablet or Placebo tablet (matching Hypertena 20 mg)

Baseline Measures

	All Study Participants
Number of Participants	130
Age Continuous [units: years] Mean ± Standard Deviation	40.3 ± 5.6
Gender, Male/Female [units: participants]	
Female	60
Male	70
Region of Enrollment [units: participants]	130
United States	
Study Specific Characteristic [Weight] [units: kg] Mean ± Standard Deviation	65 ± 11.2
Study Specific Characteristic [Sitting Systolic Blood Pressure (SBP)] [units: mmHg] Mean ± Standard Deviation	146.9 ± 19.9
Study Specific Characteristic [Sitting Diastolic Blood Pressure (DBP)] [units: mmHg] Mean ± Standard Deviation	91.8 ± 9.3

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Change From Baseline in Mean Sitting Systolic Blood Pressure (SBP) at 2 Weeks
Measure Description	Blood pressure was assessed after the participant was in a seated position for at least 5 minutes. Blood pressure was measured with an automated measurement device 3 times at 1 to 2 minute intervals and a mean of the 3 measurements was calculated.
Time Frame	Baseline and 2 Weeks
Safety Issue?	No

Population Description -- *Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate:*

All participants who received at least one dose of each intervention and completed all study visits were included in the efficacy analysis.

Reporting Groups

	Description
Hypertena	Participants who received Hypertena 20 mg tablet in a fasting state each morning in either the first or last 2 weeks of the study.
Placebo	Participants who received Placebo tablet (matching Hypertena 20 mg) in a fasting state each morning in either the first or last 2 weeks of the study.

Measured Values

	Hypertena	Placebo
Number of Participants Analyzed	127	123
Change From Baseline in Mean Sitting Systolic Blood Pressure (SBP) at 2 Weeks [units: mmHg] Mean ± Standard Deviation		
SBP at Baseline	146 ± 19.7	148 ± 18.6
Change from Baseline at 2 weeks	-13.7 ± 1.7	-7.0 ± 1.8

Statistical Analysis 1 for Change From Baseline in Mean Sitting Systolic Blood Pressure

(SBP) at 2 Weeks

Groups	Hypertena, Placebo
Method	ANCOVA
P-Value	<0.001

Additional details about the analysis, such as null hypothesis and power calculation:

Null hypothesis is that there was no difference in change of SBP between Hypertena and Placebo. ANCOVA models with the trough SBP at baseline, body weight, and age as covariates, and the treatment group and study site as factors. The test was performed with a significance level of 0.05 (two-sided).

A sample size of 125 participants was needed to provide 90% power to detect a 5 mmHg difference in systolic blood pressure.

Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

[Not specified.]

Other relevant information, such as adjustments or degrees of freedom:

[Not specified.]

2. Primary Outcome Measure:

Measure Title	Change From Baseline in Mean Sitting Diastolic Blood Pressure (DBP) at 2 Weeks
Measure Description	Blood pressure was assessed after the participant was in a seated position for at least 5 minutes. Blood pressure was measured with an automated measurement device 3 times at 1 to 2 minute intervals and a mean of the 3 measurements was calculated.
Time Frame	Baseline and 2 Weeks
Safety Issue?	No

Population Description -- *Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate:*

All participants who received at least one dose of each intervention and completed all study visits were included in the efficacy analysis.

Reporting Groups

Description

Hypertena	Participants who received Hypertena 20 mg tablet in a fasting state each morning in either the first or last 2 weeks of the study.
Placebo	Participants who received Placebo tablet (matching Hypertena 20 mg) in a fasting state each morning in either the first or last 2 weeks of the study.

Measured Values

	Hypertena	Placebo
Number of Participants Analyzed	127	123
Change From Baseline in Mean Sitting Diastolic Blood Pressure (DBP) at 2 Weeks		
<i>[units: mmHg]</i>		
Mean ± Standard Deviation		
DBP at Baseline	92 ± 9.2	91 ± 9.1
Change from Baseline at 2 weeks	-6.8 ± 1.3	-2.7 ± 0.7

Statistical Analysis 1 for Change From Baseline in Mean Sitting Diastolic Blood Pressure (DBP) at 2 Weeks

Groups	Hypertena, Placebo
Method	ANCOVA
P-Value	<0.001

Additional details about the analysis, such as null hypothesis and power calculation:

Null hypothesis is that there was no difference in change of DBP between Hypertena and Placebo. ANCOVA models with the trough DBP at baseline, body weight, and age as covariates, and the treatment group and study site as factors. The test was performed with a significance level of 0.05 (two-sided).

Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

[Not specified.]

Other relevant information, such as adjustments or degrees of freedom:

[Not specified.]

3. Secondary Outcome Measure:

Measure Title	Percentage of Participants With Response
Measure Description	Percentage of participants achieving a mean sitting systolic blood pressure < 140 mmHg and a mean sitting diastolic blood pressure < 90 mmHg at 2

	weeks (Response Rate)
Time Frame	2 Weeks
Safety Issue?	No

Population Description -- *Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate:*

All participants who received at least one dose of each intervention and completed all study visits were included in the efficacy analysis.

Reporting Groups

	Description
Hypertena	Participants who received Hypertena 20 mg tablet in a fasting state each morning in either the first or last 2 weeks of the study.
Placebo	Participants who received Placebo tablet (matching Hypertena 20 mg) in a fasting state each morning in either the first or last 2 weeks of the study.

Measured Values

	Hypertena	Placebo
Number of Participants Analyzed	127	123
Percentage of Participants With Response <i>[units: percentage of participants]</i>	45	35

Reported Adverse Events

Reporting Groups

	Description
Hypertena	Participants received Hypertena 20 mg tablet in a fasting state each morning for 2 weeks.
Placebo	Participants received Placebo tablet (matching Hypertena 20 mg) in a fasting state each morning for 2 weeks.

Time Frame	Two weeks for each Intervention.
Additional Description	Safety Population included all participants who received at least one dose of intervention.

Serious Adverse Events

	Hypertena	Placebo

Total # participants affected/at risk 0/127 (0%) 1/127 (0.79%)

Cardiac disorders

Myocardial Infarction † A

participants affected/at risk 0/127 (0%) 1/127 (0.79%)

† Indicates events were collected by systematic assessment.

A Term from vocabulary, MedDRA 11.1

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 0%

	Hypertena	Placebo
Total # participants affected/at risk	49/127 (38.58%)	33/127 (25.98%)
Gastrointestinal disorders		
Nausea † A		
# participants affected/at risk	10/127 (7.87%)	5/127 (3.94%)
Infections and infestations		
Influenza † A		
# participants affected/at risk	2/127 (1.57%)	1/127 (0.79%)
Nervous system disorders		
Dizziness † A		
# participants affected/at risk	11/127 (8.66%)	6/127 (4.72%)
Headache † A		
# participants affected/at risk	20/127 (15.75%)	16/127 (12.6%)
Restlessness † A		
# participants affected/at risk	5/127 (3.94%)	4/127 (3.15%)
Psychiatric disorders		
Depression † A		
# participants affected/at risk	1/127 (0.79%)	1/127 (0.79%)

† Indicates events were collected by systematic assessment.

A Term from vocabulary, MedDRA (11.1)

More Information

Certain Agreements:

All Principal Investigators ARE employed by the organization sponsoring the study.

Limitations and Caveats -- *Limitations of the study, such as early termination leading to small numbers of subjects analyzed and technical problems with measurement leading to unreliable or uninterpretable data:*

[Not specified.]

Results Point of Contact:

Name/Official Title: PRS Training Lead

Organization: PRS Training

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Email: register@clinicaltrials.gov

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