Cross-Over Study Design Example (With Results)

This study has been completed.

Sponsor: PRS Results Training

Information provided by (Responsible Party): PRS Results Training

Disclaimer: The following information is fictional and is only intended for the purpose of illustrating key concepts for results data entry in the Protocol Registration and Results System (PRS).

Full Text View

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: Allocation: Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Crossover Assignment
Masking: Double Blind (Subject, Investigator)
Primary Purpose: Treatment

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 Results Training

Primary Outcome Measures:

- 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
Experimental: 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 tablet) in a fasting state each morning for 2 weeks.	Drug: Hypertena 20 mg tablet Drug: Placebo Hypertena-matched Placebo tablet
Experimental: Placebo, Then Hypertena 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.	Drug: Hypertena 20 mg tablet Drug: Placebo Hypertena-matched Placebo tablet

Detailed Description

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
Accepts Healthy Volunteers: No

Inclusion Criteria

- Diagnosed with high blood pressure (Stage 1 or 2 hypertension per Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7): Systolic blood pressure (SBP) ≥ 140 mmHg and/or diastolic blood pressure (DBP) ≥ 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: PRS Results Training
Study ID Numbers: TTTCrossoverR
Health Authority: United States: Food and Drug Administration

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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 Springfield, 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 in a fasting state each morning for 2 weeks.

First Intervention (2 Weeks)

	Number of Participants	
	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)

	Number of Participants	
	Hypertena, Then Placebo	**Placebo, Then Hypertena**
STARTED	**65**	**63**
COMPLETED	**63**	**62**
Not Completed	**2**	**1**
Disease relapse	2	1

Second Intervention (2 Weeks)

	Number of Participants	
	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

Baseline Characteristics

Analysis 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.)

[No text entered.]

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]	
United States	130
Weight [units: kg] Mean ± Standard Deviation	65 ± 11.2
Sitting Systolic Blood Pressure (SBP) [units: mmHg] Mean ± Standard Deviation	146.9 ± 19.9
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

Analysis 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[A]	Hypertena, Placebo
Method	ANCOVA
P-Value	<0.001

[A] 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.

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

Analysis 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 [units: mmHg] 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 [A]	Hypertena, Placebo
Method	ANCOVA
P-Value	<0.001

[A] 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).

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

Analysis 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 [units: percentage of participants]	45	35

Adverse Events

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

Reporting Groups

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

Serious Adverse Events

	# Participants Affected/At Risk	
	Hypertena	Placebo
Total, serious adverse events	**0/127 (0%)**	**1/127 (0.79%)**
Cardiac disorders		
Myocardial Infarction †1	0/127 (0%)	1/127 (0.79%)

† Indicates events were collected by systematic assessment.
1 Term from vocabulary, MedDRA 11.1

Other Adverse Events

Frequency Threshold

Threshold above which other adverse events are reported: 0%

	# Participants Affected/At Risk	
	Hypertena	Placebo
Total, other (not including serious) adverse events	**49/127 (38.58%)**	**33/127 (25.98%)**
Gastrointestinal disorders		
Nausea †1	10/127 (7.87%)	5/127 (3.94%)
Infections and infestations		
Influenza †1	2/127 (1.57%)	1/127 (0.79%)
Nervous system disorders		
Dizziness †1	11/127 (8.66%)	6/127 (4.72%)
Headache †1	20/127 (15.75%)	16/127 (12.60%)
Restlessness †1	5/127 (3.94%)	4/127 (3.15%)
Psychiatric disorders		
Depression †1	1/127 (0.79%)	1/127 (0.79%)

† Indicates events were collected by systematic assessment.
1 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.)

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Results Point of Contact

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