Cross-Over Study Design Example (With Results)

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).

ClinicalTrials.gov Identifier: NCT00055568

Recruitment Status: Completed
First Posted: May 3, 2017
Results First Posted: February 10, 2019
Last Update Posted: February 10, 2019

Sponsor:

PRS Results Training

Information provided by (Responsible Party):

PRS Results Training

Study Description

Brief Summary:

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 or disease	Intervention/treatment	Phase
High Blood Pressure	Drug: Hypertena Drug: Placebo	Phase 2

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.

Study Design

Study Type:	Interventional
Actual Enrollment:	130 participants
Allocation:	Randomized
Intervention Model:	Crossover Assignment
Masking:	Double (Participant, Investigator)
Primary Purpose:	Treatment
Official Title:	Phase II, Randomized, Double-Blind, Cross-Over Study of Hypertena and Placebo in Participants With High Blood Pressure
Actual Study Start Date:	May 3, 2017
Actual Primary Completion Date:	February 11, 2018
Actual Study Completion Date:	February 11, 2018

Arms and Interventions

Arm	Intervention/treatment
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

Outcome Measures

Primary Outcome Measures:

1. Change From Baseline in Mean Sitting Systolic Blood Pressure (SBP) at 2 Weeks [Time Frame: Baseline and 2 Weeks]

   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.

2. Change From Baseline in Mean Sitting Diastolic Blood Pressure (DBP) at 2 Weeks [Time Frame: Baseline and 2 Weeks]

   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 Measure:

1. Number of Participants With Response [Time Frame: 2 weeks]

   Number 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)

Eligibility Criteria

Ages Eligible for Study: 18 Years and older (Adult, Older Adult)
Sexes Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Diagnosed with high blood pressure (Stage 1 or 2 hypertension via 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

St. Emanuel Hospital

Springfield, Illinois, United States, 62715

Study Documents (Full-Text)

Documents provided by PRS Results Training

Study Protocol and Statistical Analysis Plan [PDF] April 3, 2017

More Information

Responsible Party:	PRS Results Training
ClinicalTrials.gov Identifier:	NCT00055568
Other Study ID Numbers:	TTTCrossoverR
First Posted:	May 3, 2017
Results First Posted:	February 10, 2019
Last Update Posted:	February 10, 2019
Last Verified:	January 2019

Human Subjects Protection Review Board Status:	Approved
Studies a U.S. FDA-regulated Drug Product:	Yes
Studies a U.S. FDA-regulated Device Product:	No

Study Results

Study Type	Interventional
Study Design	Allocation: Randomized; Intervention Model: Crossover Assignment; Masking: Double (Participant, Investigator); Primary Purpose: Treatment
Condition	High Blood Pressure
Interventions	Drug: Hypertena Drug: Placebo
Enrollment	130

Participant Flow

Recruitment Details	200 patients were screened for eligibility between May 3, 2017 and October 24, 2017 at a hospital-associated specialty clinic in Springfield, IL.
Pre-assignment Details	130 of 200 participants were randomized. Of those not randomized, 35 did not meet inclusion criteria and 35 declined to participate.

Arm/Group Title	Hypertena, Then Placebo	Placebo, Then Hypertena
Arm/Group Description	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.	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.

Period Title: **First Intervention (2 Weeks)**		
Started	65	65
Received Intervention	65	64
Completed	65	63
Not Completed	0	2
Reason Not Completed		
Withdrawal by Subject	0	1
Adverse Event	0	1
Period Title: **Washout (2 Weeks)**		
Started	65	63
Completed	63	62
Not Completed	2	1
Reason Not Completed		
Disease relapse	2	1
Period Title: **Second Intervention (2 Weeks)**		
Started	63	62
Completed	60	62
Not Completed	3	0
Reason Not Completed		
Adverse Event	2	0
Lost to Follow-up	1	0

Baseline Characteristics

Arm/Group Title		Hypertena, Then Placebo	Placebo, Then Hypertena	Total
Arm/Group Description		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.	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.	Total of all reporting groups
Overall Number of Baseline Participants		65	65	130
Baseline Analysis Population Description		[Not Specified]		
Age, Continuous Mean (Standard Deviation) Unit of Measure: years				
	Number Analyzed	65 participants	65 participants	130 participants
		40.5 (5.3)	40.1 (5.9)	40.3 (5.6)

Sex: Female, Male Measure Type: Count of Participants Unit of measure: participants				
	Number Analyzed	65 participants	65 participants	130 participants
	Female	31 47.69%	29 44.62%	60 46.15%
	Male	34 52.31%	36 55.38%	70 53.85%
Ethnicity (NIH/OMB) Measure Type: Count of Participants Unit of measure: participants				
	Number Analyzed	65 participants	65 participants	130 participants
	Hispanic or Latino	13 20%	12 18.46%	25 19.23%
	Not Hispanic or Latino	52 80%	53 81.54%	105 80.77%
	Unknown or Not Reported	0 0%	0 0%	0 0%

Race (NIH/OMB) Measure Type: Count of Participants Unit of measure: participants				
	Number Analyzed	65 participants	65 participants	130 participants
	American Indian or Alaska Native	0 0%	0 0%	0 0%
	Asian	0 0%	0 0%	0 0%
	Native Hawaiian or Other Pacific Islander	0 0%	0 0%	0 0%
	Black or African American	10 15.38%	9 13.85%	19 14.62%
	White	55 84.62%	56 86.15%	111 85.38%
	More than one race	0 0%	0 0%	0 0%
	Unknown or Not Reported	0 0%	0 0%	0 0%
Region of Enrollment Measure Type: Count of Participants Unit of measure: participants				
United States	Number Analyzed	65 participants	65 participants	130 participants
		65 100%	65 100%	130 100%

Weight Mean (Standard Deviation) Unit of measure: kg				
	Number Analyzed	65 participants	65 participants	130 participants
		63.9 (8.9)	66.1 (13.0)	65.0 (11.2)
Sitting Systolic Blood Pressure (SBP) Mean (Standard Deviation) Unit of measure: mmHg				
	Number Analyzed	65 participants	65 participants	130 participants
		143.9 (15.5)	149.9 (23.1)	146.9 (19.9)
Sitting Diastolic Blood Pressure (DBP) Mean (Standard Deviation) Unit of measure: mmHg				
	Number Analyzed	65 participants	65 participants	130 participants
		89.9 (8.6)	93.7 (9.6)	91.8 (9.3)

Outcome Measures

1. Primary Outcome

Title	Change From Baseline in Mean Sitting Systolic Blood Pressure (SBP) at 2 Weeks
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

Outcome Measure Data

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

Arm/Group Title	Hypertena	Placebo
Arm/Group Description:	Participants who received Hypertena 20 mg tablet in a fasting state each morning in either the first or last 2 weeks of the study.	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.
Overall Number of Participants Analyzed	127	123
Mean (Standard Deviation) Unit of Measure: mmHg		
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

Statistical Analysis Overview	Comparison Group Selection	Hypertena, Placebo
	Comments	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.
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	<0.001
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

2. Primary Outcome

Title	Change From Baseline in Mean Sitting Diastolic Blood Pressure (DBP) at 2 Weeks
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

Outcome Measure Data

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

Arm/Group Title	Hypertena	Placebo
Arm/Group Description:	Participants who received Hypertena 20 mg tablet in a fasting state each morning in either the first or last 2 weeks of the study.	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.
Overall Number of Participants Analyzed	127	123
Mean (Standard Deviation) Unit of Measure: mmHg		
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

Statistical Analysis Overview	Comparison Group Selection	Hypertena, Placebo
	Comments	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).
	Type of Statistical Test	Superiority
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	<0.001
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

3. Secondary Outcome

Title	Number of Participants With Response
Description	Number 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

Outcome Measure Data

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

Arm/Group Title	Hypertena	Placebo
Arm/Group Description:	Participants who received Hypertena 20 mg tablet in a fasting state each morning in either the first or last 2 weeks of the study.	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.
Overall Number of Participants Analyzed	127	123
Measure Type: Count of Participants Unit of Measure: participants	57 44.88%	43 34.96%

Adverse Events

Time Frame	Two weeks for each intervention.
Adverse Event Reporting Description	Safety Population included all participants who received at least one dose of intervention.
Source Vocabulary Name for Table Default	MedDRA (11.1)
Collection Approach for Table Default	Systematic Assessment

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

All-Cause Mortality

	Hypertena	Placebo
	Affected / at Risk (%)	Affected / at Risk (%)
Total	0/127 (0%)	0/127 (0%)

Serious Adverse Events

	Hypertena	Placebo
	Affected / at Risk (%)	Affected / at Risk (%)
Total	0/127 (0%)	1/127 (0.79%)
Cardiac disorders		
Myocardial Infarction †1	0/127 (0%)	1/127 (0.79%)

1 Term from vocabulary, MedDRA (11.1)

† Indicates events were collected by systematic assessment

Other (Not Including Serious) Adverse Events

Frequency Threshold for Reporting Other Adverse Events	0%	
	Hypertena	**Placebo**
	Affected / at Risk (%)	Affected / at Risk (%)
Total	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 (12.6%)
Restlessness †1	5/127 (3.94%)	4/127 (3.15%)
Psychiatric disorders		
Depression †1	1/127 (0.79%)	1/127 (0.79%)

1 Term from vocabulary, MedDRA (11.1)

† Indicates events were collected by systematic assessment

Limitations and Caveats

[Not Specified]

More Information

Certain Agreements

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

Results Point of Contact

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Organization: PRS Results Training

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Responsible Party:	PRS Results Training
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