Parallel 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: NCT00055555

Recruitment Status: Completed
First Posted: March 1, 2017
Results First Posted: May 30, 2019
Last Update Posted: May 30, 2019

Sponsor:

PRS Results Training

Information provided by (Responsible Party):

PRS Results Training

Study Description

Brief Summary:

The purpose of this study is to assess the safety and efficacy of Remuverol for treatment of disc herniation.

Condition or disease	Intervention/treatment	Phase
Herniated Disc	Drug: Remuverol Drug: Placebo	Phase 3

Detailed Description:

After being informed about the study and potential risks, all patients giving written informed consent will undergo a 1-week screening period to determine eligibility for study entry. At week 0, patients who meet the eligibility requirements will be randomized in a double-blind manner (participant and investigator) in a 1:1 ratio to Remuverol (15 mg, twice daily) or placebo (twice daily).

Study Design

Study Type:	Interventional
Actual Enrollment:	205 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	Double (Participant, Investigator)
Primary Purpose:	Treatment
Official Title:	A 24-Week Double-Blind Trial of Remuverol in Adults With Disc Herniation
Actual Study Start Date:	March 1, 2017
Actual Primary Completion Date:	June 1, 2018
Actual Study Completion Date:	August 1, 2018

Arms and Interventions

Arm	Intervention/treatment
Experimental: Remuverol Participants received Remuverol 15 mg tablet orally twice daily for 24 weeks.	Drug: Remuverol 15 mg tablet
Placebo Comparator: Placebo Participants received Remuverol placebo tablet matching Remuverol orally twice daily for 24 weeks.	Drug: Placebo Remuverol placebo tablet

Outcome Measures

Primary Outcome Measure:

1. Change From Baseline in Pain on the 11-point Short Pain Scale (SPS-11) at Week 24 [Time Frame: Baseline and Week 24]

   SPS-11 is a validated, self-reported instrument assessing average pain intensity over the past 24 hour period. Possible scores range from 0 (no pain) to 10 (worst possible pain). Change = (Week 24 Score - Baseline Score).

Secondary Outcome Measures:

1. Response Rate - 50 Percent or Greater Reduction in Short Pain Scale (SPS-11) Score [Time Frame: 12 weeks]

   The response rate was defined as the number of participants with a 50% or greater reduction in SPS-11 pain score from baseline to endpoint. SPS-11 is a validated, self-reported instrument assessing average pain intensity over the past 24 hour period. Possible scores range from 0 (no pain) to 10 (worst possible pain).

2. Response Rate - 50 Percent or Greater Reduction in Short Pain Scale (SPS-11) Score [Time Frame: 24 weeks]

   The response rate was defined as the number of participants with a 50% or greater reduction in SPS-11 pain score from baseline to endpoint. SPS-11 is a validated, self-reported instrument assessing average pain intensity over the past 24 hour period. Possible scores range from 0 (no pain) to 10 (worst possible pain).

3. Response Rate - 75 Percent or Greater Reduction in Short Pain Scale (SPS-11) Score [Time Frame: 24 weeks]

   The response rate was defined as the number of participants with a 75% or greater reduction in SPS-11 pain score from baseline to endpoint. SPS-11 is a validated, self-reported instrument assessing average pain intensity over the past 24 hour period. Possible scores range from 0 (no pain) to 10 (worst possible pain).

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:

- Outpatients
- At least 18 years of age
- Had disc herniation for at least 6 months before the study. Disc herniation was diagnosed based on medical history and neurological examination.
- A sufficient level of education to understand study procedures and be able to communicate with site personnel

Exclusion Criteria:

- Any cardiovascular, hepatic, or renal conditions that would compromise participation (e.g., hospitalization during the study), in the opinion of the investigator
- History of acute liver injury (e.g., hepatitis) or severe cirrhosis
- Body Mass Index (BMI) of >40 kg/m^2
- Pregnancy
- Breast-feeding
- Daily use of non-steroidal anti-inflammatory drugs (NSAIDs) or acetaminophen
- Current use of narcotics

Contacts and Locations

Locations

United States, Maryland

NIH

Bethesda, Maryland, United States, 20892

Canada, Quebec

McGill University

Montreal, Quebec, Canada

Mexico

University of Quintana Roo

Cozumel, Mexico

Study Documents (Full-Text)

Documents provided by PRS Results Training

Study Protocol and Statistical Analysis Plan [PDF] February 1, 2016

More Information

Responsible Party:	PRS Results Training
ClinicalTrials.gov Identifier:	NCT00055555
Other Study ID Numbers:	TTTParallelR
First Posted:	March 1, 2017

Results First Posted: May 30, 2019
Last Update Posted: May 30, 2019
Last Verified: May 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: Parallel Assignment; Masking: Double (Participant, Investigator); Primary Purpose: Treatment
Condition	Herniated Disc
Interventions	Drug: Remuverol Drug: Placebo
Enrollment	205

Participant Flow

Recruitment Details	Participants were recruited based on physician referral at 3 academic medical centers between February 2017 and January 2018. The first participant was enrolled on March 1, 2017 and the last participant was enrolled in December 2017.
Pre-assignment Details	Of 205 enrolled participants, 200 met inclusion criteria and were randomized to treatment.

Arm/Group Title	Remuverol	Placebo
Arm/Group Description	Participants received Remuverol 15 mg tablet orally twice daily for 24 weeks. Remuverol: 15 mg tablet	Participants received Remuverol placebo tablet matching Remuverol orally twice daily for 24 weeks. Placebo: Remuverol placebo tablet
Period Title: **Overall Study**		
Started	101	99
Per Protocol Population Week 12	98	95
Per Protocol Population Week 24	76	81
Completed	80	81
Not Completed	21	18
Reason Not Completed		
Adverse Event	10	8
Withdrawal by Subject	5	4
Protocol Violation	2	2
Lack of Efficacy	1	1
Physician Decision	1	1
Lost to Follow-up	1	2
Pregnancy	1	0

Baseline Characteristics

Arm/Group Title		Remuverol	Placebo	Total
Arm/Group Description		Participants received Remuverol 15 mg tablet orally twice daily for 24 weeks. Remuverol: 15 mg tablet	Participants received Remuverol placebo tablet matching Remuverol orally twice daily for 24 weeks. Placebo: Remuverol placebo tablet	Total of all reporting groups
Overall Number of Baseline Participants		101	99	200
Baseline Analysis Population Description		[Not Specified]		
Age, Continuous Mean (Standard Deviation) Unit of Measure: years				
	Number Analyzed	101 participants	99 participants	200 participants
		34.78 (9.72)	35.34 (10.71)	35.06 (10.23)
Sex: Female, Male Measure Type: Count of Participants Unit of measure: participants				
	Number Analyzed	101 participants	99 participants	200 participants
	Female	60 59.41%	63 63.64%	123 61.5%
	Male	41 40.59%	36 36.36%	77 38.5%

Ethnicity (NIH/OMB) Measure Type: Count of Participants Unit of measure: participants							
	Number Analyzed	101 participants		99 participants		200 participants	
	Hispanic or Latino	5	4.95%	4	4.04%	9	4.5%
	Not Hispanic or Latino	96	95.05%	95	95.96%	191	95.5%
	Unknown or Not Reported	0	0%	0	0%	0	0%
Race (NIH/OMB) Measure Type: Count of Participants Unit of measure: participants							
	Number Analyzed	101 participants		99 participants		200 participants	
	American Indian or Alaska Native	1	0.99%	1	1.01%	2	1%
	Asian	0	0%	0	0%	0	0%
	Native Hawaiian or Other Pacific Islander	0	0%	0	0%	0	0%
	Black or African American	5	4.95%	4	4.04%	9	4.5%
	White	95	94.06%	94	94.95%	189	94.5%
	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	Number Analyzed	101 participants		99 participants		200 participants	
Canada		35	34.65%	35	35.35%	70	35%
United States		44	43.56%	47	47.47%	91	45.5%
Mexico		22	21.78%	17	17.17%	39	19.5%
Quebec Task Force Classification of Spinal Disorders [1] Measure Type: Count of Participants Unit of measure: participants							
	Number Analyzed	101 participants		99 participants		200 participants	
	Class 0 (no pain)	16	15.84%	14	14.14%	30	15%
	Class 1 (pain without radiation)	73	72.28%	68	68.69%	141	70.5%
	Class 2 (pain with proximal extremity radiation)	12	11.88%	17	17.17%	29	14.5%
		[1] Measure Description: Quebec Task Force (QTF) Classification of Spinal Disorders consists of 8 classes ranging from Class 0 (no pain) to Class 7 (spinal stenosis).					

Body Mass Index Mean (Standard Deviation) Unit of measure: kg/m^2				
	Number Analyzed	101 participants	99 participants	200 participants
		26.65 (4.50)	27.41 (4.72)	27.03 (4.63)
Short Pain Scale (SPS-11) Score [1] Mean (Standard Deviation) Unit of measure: units on a scale				
	Number Analyzed	101 participants	99 participants	200 participants
		6.48 (1.34)	6.57 (1.73)	6.52 (1.55)
		[1] Measure Description: SPS-11 is a validated, self-reported instrument assessing average pain intensity over the past 24 hr period. The severity of pain on the SPS-11 ranges from 0 (no pain) to 10 (worst possible pain).		
Duration of Disc Herniation Mean (Standard Deviation) Unit of measure: years				
	Number Analyzed	101 participants	99 participants	200 participants
		3.82 (3.18)	3.47 (2.95)	3.65 (3.07)

Height Mean (Standard Deviation) Unit of measure: cm				
	Number Analyzed	101 participants	99 participants	200 participants
		186.42 (9.46)	176.91 (8.28)	181.71 (10.09)
Weight Mean (Standard Deviation) Unit of measure: kg				
	Number Analyzed	101 participants	99 participants	200 participants
		77.03 (14.38)	78.53 (13.56)	77.77 (14.00)

Outcome Measures

1. Primary Outcome

Title	Change From Baseline in Pain on the 11-point Short Pain Scale (SPS-11) at Week 24
Description	SPS-11 is a validated, self-reported instrument assessing average pain intensity over the past 24 hour period. Possible scores range from 0 (no pain) to 10 (worst possible pain). Change = (Week 24 Score – Baseline Score).
Time Frame	Baseline and Week 24

Outcome Measure Data

Analysis Population Description
Intent to Treat population (all participants assigned to Remuverol or Placebo). Last observation carried forward (LOCF) imputation method.

Arm/Group Title	Remuverol	Placebo
Arm/Group Description:	Participants received Remuverol 15 mg tablet orally twice daily for 24 weeks. Remuverol: 15 mg tablet	Participants received Remuverol placebo tablet matching Remuverol orally twice daily for 24 weeks. Placebo: Remuverol placebo tablet
Overall Number of Participants Analyzed	101	99
Mean (Standard Deviation) Unit of Measure: units on a scale	-3.84 (0.61)	-2.08 (0.51)

Statistical Analysis 1

Statistical Analysis Overview	Comparison Group Selection	Remuverol, Placebo
	Comments	It was calculated that 200 participants randomized in a 1:1 fashion between the 2 arms would have at least 85% power to detect a difference of 0.56 points in mean SPS-11 pain score between Remuverol and placebo from baseline to week 24. Sample size was determined using a 2-sided 2-sample t test (α = 0.05). Assumptions included a common standard deviation of 1.14 and a discontinuation rate of 7%.
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.002
	Comments	The threshold for statistical significance was p = 0.05.
	Method	Mixed Models Analysis
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Mean Difference (Net)
	Estimated Value	-1.76
	Parameter Dispersion	Type:Standard Deviation Value: 0.80
	Estimation Comments	Treatment Difference = Remuverol - Placebo

2. Secondary Outcome

Title	Response Rate - 50 Percent or Greater Reduction in Short Pain Scale (SPS-11) Score
Description	The response rate was defined as the number of participants with a 50% or greater reduction in SPS-11 pain score from baseline to endpoint. SPS-11 is a validated, self-reported instrument assessing average pain intensity over the past 24 hour period. Possible scores range from 0 (no pain) to 10 (worst possible pain).
Time Frame	12 weeks

Outcome Measure Data

Analysis Population Description
Per-protocol population (all participants with baseline and week 12 pain scores available).

Arm/Group Title	Remuverol	Placebo
Arm/Group Description:	Participants received Remuverol 15 mg tablet orally twice daily for 24 weeks. Remuverol: 15 mg tablet	Participants received Remuverol placebo tablet matching Remuverol orally twice daily for 24 weeks. Placebo: Remuverol placebo tablet
Overall Number of Participants Analyzed	98	95
Measure Type: Count of Participants Unit of Measure: participants	45 45.92%	37 38.95%

Statistical Analysis 1

Statistical Analysis Overview	Comparison Group Selection	Remuverol, Placebo
	Comments	[Not specified]
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.383
	Comments	[Not specified]
	Method	Fisher Exact
	Comments	[Not specified]

3. Secondary Outcome

Title	Response Rate - 50 Percent or Greater Reduction in Short Pain Scale (SPS-11) Score
Description	The response rate was defined as the number of participants with a 50% or greater reduction in SPS-11 pain score from baseline to endpoint. SPS-11 is a validated, self-reported instrument assessing average pain intensity over the past 24 hour period. Possible scores range from 0 (no pain) to 10 (worst possible pain).
Time Frame	24 weeks

Outcome Measure Data

Analysis Population Description
Per-protocol population (all participants with baseline and week 24 pain scores available).

Arm/Group Title	Remuverol	Placebo
Arm/Group Description:	Participants received Remuverol 15 mg tablet orally twice daily for 24 weeks. Remuverol: 15 mg tablet	Participants received Remuverol placebo tablet matching Remuverol orally twice daily for 24 weeks. Placebo: Remuverol placebo tablet
Overall Number of Participants Analyzed	76	81
Measure Type: Count of Participants Unit of Measure: participants	73 96.05%	67 82.72%

Statistical Analysis 1

Statistical Analysis Overview	Comparison Group Selection	Remuverol, Placebo
	Comments	[Not specified]
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.009
	Comments	[Not specified]
	Method	Fisher Exact
	Comments	[Not specified]

4. Secondary Outcome

Title	Response Rate - 75 Percent or Greater Reduction in Short Pain Scale (SPS-11) Score
Description	The response rate was defined as the number of participants with a 75% or greater reduction in SPS-11 pain score from baseline to endpoint. SPS-11 is a validated, self-reported instrument assessing average pain intensity over the past 24 hour period. Possible scores range from 0 (no pain) to 10 (worst possible pain).
Time Frame	24 weeks

Outcome Measure Data

Analysis Population Description
Per-protocol population (all participants with baseline and week 24 pain scores available).

Arm/Group Title	Remuverol	Placebo
Arm/Group Description:	Participants received Remuverol 15 mg tablet orally twice daily for 24 weeks. Remuverol: 15 mg tablet	Participants received Remuverol placebo tablet matching Remuverol orally twice daily for 24 weeks. Placebo: Remuverol placebo tablet
Overall Number of Participants Analyzed	76	81
Measure Type: Count of Participants Unit of Measure: participants	57 75%	32 39.51%

Statistical Analysis 1

Statistical Analysis Overview	Comparison Group Selection	Remuverol, Placebo
	Comments	[Not Specified]
	Type of Statistical Test	Superiority
	Comments	[Not Specified]

Statistical Test of Hypothesis	P-Value	0.006
	Comments	[Not Specified]
	Method	Fisher Exact
	Comments	[Not Specified]

Adverse Events

Time Frame	32 Weeks	
Adverse Event Reporting Description		
Source Vocabulary Name for Table Default	MedDRA (12.0)	
Collection Approach for Table Default	Systematic Assessment	
Arm/Group Title	Remuverol	Placebo
Arm/Group Description	Participants received Remuverol 15 mg tablet orally twice daily for 24 weeks. Remuverol: 15 mg tablet	Participants received Remuverol placebo tablet matching Remuverol orally twice daily for 24 weeks. Placebo: Remuverol placebo tablet

All-Cause Mortality

	Remuverol	**Placebo**
	Affected / at Risk (%)	Affected / at Risk (%)
Total	0/101 (0%)	0/99 (0%)

Serious Adverse Events

	Remuverol	Placebo
	Affected / at Risk (%)	Affected / at Risk (%)
Total	4/101 (3.96%)	0/99 (0%)
Blood and lymphatic system disorders		
Anemia iron deficiency †[1]	1/101 (0.99%)	0/99 (0%)
Idiopathic thrombocytopenic purpura †[1]	1/101 (0.99%)	0/99 (0%)
Immune system disorders		
Viral meningitis †[1]	1/101 (0.99%)	0/99 (0%)
Skin and subcutaneous tissue disorders		
Psoriasis †[1]	1/101 (0.99%)	0/99 (0%)

1 Term from vocabulary, MedDRA (12.0)

† Indicates events were collected by systematic assessment

Other (Not Including Serious) Adverse Events

Frequency Threshold for Reporting Other Adverse Events	1%

	Remuverol	Placebo
	Affected / at Risk (%)	Affected / at Risk (%)
Total	98/101 (97.03%)	46/99 (46.46%)
Ear and labyrinth disorders		
Earache †[1]	35/101 (34.65%)	7/99 (7.07%)
Endocrine disorders		
Hypothyroidism †[1]	27/101 (26.73%)	25/99 (25.25%)
Eye disorders		
Conjunctivitis †[1]	13/101 (12.87%)	4/99 (4.04%)
Gastrointestinal disorders		
Nausea †[1]	12/101 (11.88%)	7/99 (7.07%)
Stomachache †[1]	10/101 (9.9%)	2/99 (2.02%)
Vomiting †[1]	10/101 (9.9%)	3/99 (3.03%)

1 Term from vocabulary, MedDRA (12.0)

† Indicates events were collected by systematic assessment

Limitations and Caveats

The actual discontinuation rate was higher than expected/anticipated. Therefore, the analysis of the primary outcome measure, a change from baseline to week 24 in the SPS-11 24-hour pain score, was under-powered.

More Information

Certain Agreements

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

Results Point of Contact

Name/Title: PRS Training Lead
Organization: PRS Results Training
Phone: 555-555-5555
Email: register@clinicaltrials.gov

Responsible Party: PRS Results Training
ClinicalTrials.gov Identifier: NCT00055555
Other Study ID Numbers: TTTParallelR
First Submitted: February 25, 2017
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