PRS TEST SYSTEM

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Protocol Registration System

Protocol Registration Preview

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Example Parallel Study Design***

This study has been completed.

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

Purpose

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

Condition	Intervention	Phase
Condition A	Drug: Remuverol Drug: Placebo	Phase 3

Study Type: Interventional
Study Design: Treatment, Parallel Assignment, Double Blind (Subject, Investigator), Randomized, Safety/Efficacy Study

Official Title: A 24-Week Double-Blind Trial of Remuverol in Adults With Condition A

Further study details as provided by , PRS Training:

Primary Outcome Measure:

- Change From Baseline in Pain on the 11-point Short Pain Scale (SPS-11) at Week 24 [Time Frame: Baseline and Week 24] [Designated as safety issue: No]
  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:

- Response Rate for 50 Percent or Greater Reduction in Short Pain Scale (SPS-11) Score [Time Frame: 12 weeks] [Designated as safety issue: No]
  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. Possible scores range from 0 (no pain) to 10 (worst possible pain).

- Response Rate for 50 Percent or Greater Reduction in Short Pain Scale (SPS-11) Score [Time Frame: 24 weeks] [Designated as safety issue: No]
  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. Possible scores range from 0 (no pain) to 10 (worst possible pain).

- Response Rate for 75 Percent or Greater Reduction in Short Pain Scale (SPS-11) Score [Time Frame: 24 weeks] [Designated as safety issue: No]
  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. Possible scores range from 0 (no pain) to 10 (worst possible pain).

Enrollment: 200
Study Start Date: March 2010
Study Completion Date: August 2011
Primary Completion Date: August 2011

Arms	**Assigned Interventions**
Experimental: Remuverol Participants received Remuverol 15 mg tablet orally twice daily for 24 weeks.	Drug: Remuverol 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

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).

Eligibility

Ages Eligible for Study: 18 Years and older
Genders Eligible for Study: Both

Inclusion Criteria:

- Outpatients
- At least 18 years of age
- Had Condition A for at least 6 months before the study. Condition A 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

Bethesda, Maryland, United States

Canada, Quebec

Montreal, Quebec, Canada

Mexico

Cozumel, Mexico

More Information

Responsible Party: , Information Research Specialist, PRS Training
Study ID Numbers: FDXAR
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:*

Participants were recruited based on physician referral at 3 academic medical centers between February 2010 and January 2011. The first participant was enrolled in March 2010, and the last participant was enrolled in December 2010.

Reporting Groups

	Description
Remuverol	Participants received Remuverol 15 mg tablet orally twice daily for 24 weeks.
Placebo	Participants received Remuverol placebo tablet orally twice daily for 24 weeks.

Overall Study

	Remuverol	Placebo
STARTED	101	99
Per Protocol Population Week 12	98	95
Per Protocol Population Week 24	76	81
COMPLETED	80	81
Not Completed	**21**	**18**
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

Reporting Groups

	Description
Remuverol	Participants received Remuverol 15 mg tablet orally twice daily for 24 weeks.
Placebo	Participants received Remuverol placebo tablet orally twice daily for 24 weeks.

Baseline Measures

	Remuverol	Placebo	Total
Number of Participants	101	99	**200**
Age Continuous *[units: years]* *Mean ± Standard Deviation*	34.78 ± 9.72	35.34 ± 10.71	**34.98 ± 9.89**
Gender, Male/Female *[units: participants]*			
Female	60	63	**123**
Male	41	36	**77**
Race/Ethnicity, Customized *[units: participants]*			
African	5	4	**9**
Caucasian	90	90	**180**
Hispanic	5	4	**9**
Native American	1	1	**2**
Region of Enrollment *[units: participants]*			
United States	44	47	**91**
Canada	35	35	**70**
Mexico	22	17	**39**
Study Specific Characteristic [Quebec Task Force Classification of Spinal Disorders] [1] *[units: participants]*			
Class 0 (no pain)	16	14	**30**
Class 1 (pain without radiation)	73	68	**141**
Class 2 (pain with proximal extremity radiation)	12	17	**29**
Study Specific Characteristic [Body Mass Index] *[units: kg/m^2]* *Mean ± Standard Deviation*	26.65 ± 4.50	27.41 ± 4.72	**26.91 ± 4.55**
Study Specific Characteristic [Short Pain Scale (SPS-11) Score] [2]	6.48 ± 1.34	6.57 ± 1.73	**6.52 ± 1.61**

[units: units on a scale] *Mean ± Standard Deviation*			
Study Specific Characteristic [Duration of Condition A] *[units: years]* *Mean ± Standard Deviation*	3.82 ± 3.18	3.47 ± 2.95	**3.75 ± 3.06**
Study Specific Characteristic [Height] *[units: cm]* *Mean ± Standard Deviation*	186.42 ± 9.46	176.91 ± 8.28	**181.33 ± 8.95**
Study Specific Characteristic [Weight] *[units: kg]* *Mean ± Standard Deviation*	77.03 ± 14.38	78.53 ± 13.56	**77.98 ± 13.79**

[1] Quebec Task Force (QTF) Classification of Spinal Disorders consists of 8 classes ranging from Class 0 (no pain) to Class 7 (spinal stenosis).

[2] SPS-11 is a validated, self-reported instrument assessing average pain intensity over the past 24 hr period. The severity of pain scores on the SPS-11 range from 0 (no pain) to 10 (worst possible pain).

Outcome Measures

1. Primary Outcome Measure:

Measure Title	**Change From Baseline in Pain on the 11-point Short Pain Scale (SPS-11) at Week 24**
Measure 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
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:*

Intent to treat population (all participants who received at least one dose of intervention).

Last observation carried forward (LOCF) imputation method.

Reporting Groups

	Description
Remuverol	Participants received Remuverol 15 mg tablet orally twice daily for 24 weeks.
Placebo	Participants received Remuverol placebo tablet orally twice daily for 24 weeks.

Measured Values

	Remuverol	Placebo
Number of Participants Analyzed	101	99
Change From Baseline in Pain on the 11-point Short Pain Scale (SPS-11) at Week 24 *[units: units on a scale]* Mean ± Standard Error	-3.84 ± 0.61	-2.08 ± 0.51

Statistical Analysis 1 for Change From Baseline in Pain on the 11-point Short Pain Scale (SPS-11) at Week 24

Groups	Remuverol, Placebo
Method	t-test, 2 sided
P-Value	0.002

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

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 ($\alpha = 0.05$). Assumptions included a common standard deviation of 1.14 and a discontinuation rate of 7%.

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. Secondary Outcome Measure:

Measure Title	**Response Rate for 50 Percent or Greater Reduction in Short Pain Scale (SPS-11) Score**

Measure 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. Possible scores range from 0 (no pain) to 10 (worst possible pain).
Time Frame	12 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:*

Based on the per-protocol population. All participants with baseline and week 12 pain scores available.

Reporting Groups

	Description
Remuverol	Participants received Remuverol 15 mg tablet orally twice daily for 24 weeks.
Placebo	Participants received Remuverol placebo tablet orally twice daily for 24 weeks.

Measured Values

	Remuverol	**Placebo**
Number of Participants Analyzed	98	95
Response Rate for 50 Percent or Greater Reduction in Short Pain Scale (SPS-11) Score *[units: participants]*	45	41

Statistical Analysis 1 for Response Rate for 50 Percent or Greater Reduction in Short Pain Scale (SPS-11) Score

Groups	Remuverol, Placebo
Method	Fisher Exact
P-Value	0.352

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

[Not specified.]

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	**Response Rate for 50 Percent or Greater Reduction in Short Pain Scale (SPS-11) Score**
Measure 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. Possible scores range from 0 (no pain) to 10 (worst possible pain).
Time Frame	24 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:*

Based on the per-protocol population. All participants with baseline and week 24 pain scores available.

Reporting Groups

	Description
Remuverol	Participants received Remuverol 15 mg tablet orally twice daily for 24 weeks.
Placebo	Participants received Remuverol placebo tablet orally twice daily for 24 weeks.

Measured Values

	Remuverol	**Placebo**
Number of Participants Analyzed	76	81
Response Rate for 50 Percent or Greater Reduction in Short Pain Scale (SPS-11) Score *[units: participants]*	73	52

Statistical Analysis 1 for Response Rate for 50 Percent or Greater Reduction in Short Pain Scale (SPS-11) Score

Groups	Remuverol, Placebo
Method	Fisher Exact
P-Value	0.008

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

[Not specified.]

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.]

4. Secondary Outcome Measure:

Measure Title	**Response Rate for 75 Percent or Greater Reduction in Short Pain Scale (SPS-11) Score**
Measure 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. Possible scores range from 0 (no pain) to 10 (worst possible pain).
Time Frame	24 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:*

Based on the per-protocol population. All participants with baseline and week 24 pain scores available.

Reporting Groups

	Description
Remuverol	Participants received Remuverol 15 mg tablet orally twice daily for 24 weeks.
Placebo	Participants received Remuverol placebo tablet orally twice daily for 24 weeks.

Measured Values

	Remuverol	**Placebo**
Number of Participants Analyzed	76	81
Response Rate for 75 Percent or Greater Reduction in Short Pain Scale (SPS-11) Score *[units: participants]*	57	32

Statistical Analysis 1 for Response Rate for 75 Percent or Greater Reduction in Short Pain Scale (SPS-11) Score

Groups	Remuverol, Placebo

Method	Fisher Exact
P-Value	0.006

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

[Not specified.]

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.]

Reported Adverse Events

Reporting Groups

	Description
Remuverol	Participants received Remuverol 15 mg tablet orally twice daily for 24 weeks.
Placebo	Participants received Remuverol placebo tablet orally twice daily for 24 weeks.

Time Frame	
Additional Description	

Serious Adverse Events

	Remuverol	Placebo
Total # participants affected/at risk	**4/101 (3.96%)**	**0/99 (0%)**
Blood and lymphatic system disorders		
Anemia Iron Deficiency † A		
# participants affected/at risk	1/101 (0.99%)	0/99 (0%)
Idiopathic Thrombocytopenic Purpura † A		
# participants affected/at risk	1/101 (0.99%)	0/99 (0%)
Immune system disorders		
Viral Meningitis † A		
# participants affected/at risk	1/101 (0.99%)	0/99 (0%)

Skin and subcutaneous tissue disorders		
Psoriasis † A		
# participants affected/at risk	1/101 (0.99%)	0/99 (0%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (12.0)

Other Adverse Events
Frequency Threshold Above Which Other Adverse Events are Reported: 1%

	Remuverol	Placebo
Total # participants affected/at risk	**98/101 (97.03%)**	**46/99 (46.46%)**
Ear and labyrinth disorders		
Earache † A		
# participants affected/at risk	35/101 (34.65%)	6/99 (6.06%)
Endocrine disorders		
Hypothyroidism † A		
# participants affected/at risk	27/101 (26.73%)	25/99 (25.25%)
Eye disorders		
Conjunctivitis † A		
# participants affected/at risk	13/101 (12.87%)	4/99 (4.04%)
Gastrointestinal disorders		
Nausea † A		
# participants affected/at risk	11/101 (10.89%)	6/99 (6.06%)
Stomachache † A		
# participants affected/at risk	10/101 (9.9%)	2/99 (2.02%)
Vomiting † A		
# participants affected/at risk	10/101 (9.9%)	3/99 (3.03%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (12.0)

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
Phone: 555-555-5555
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Continue Select