ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: 01/27/2016

ClinicalTrials.gov ID: NCT00533351

Study Identification

Unique Protocol ID:	201781-504
Brief Title:	Safety and Efficacy of AGN201781 in Neuropathic Pain
Official Title:	
Secondary IDs:	

Study Status

Record Verification:	January 2016
Overall Status:	Terminated [This study was terminated early due to low enrollment.]
Study Start:	March 2008
Primary Completion:	June 2008 [Actual]
Study Completion:	June 2008 [Actual]

Sponsor/Collaborators

Sponsor:	Allergan
Responsible Party:	Sponsor
Collaborators:	

Oversight

FDA Regulated?:	Yes
Applicable Trial?:	Section 801 Clinical Trial? Yes Delayed Posting? No

IND/IDE Protocol?:	No
Review Board:	Approval Status: Approved Approval Number: 22OCT07 Board Name: Ethikkommission der Medizinischen Fakultat der ChristianAlbrechts - Universitat Kiel Board Affiliation: Christian-Albrechts University of Kiel Phone: +49 (0)431 / 597-1809 Email: ethikkomm@email.uni-kiel.de
Data Monitoring?:	No
Plan to Share Data?:	
Oversight Authorities:	Germany: Federal Institute for Drugs and Medical Devices Australia: Therapeutic Goods Agency

Study Description

Brief Summary:	This study will explore the safety and efficacy of AGN201781 in patients with postherpetic neuralgia or post-traumatic peripheral neuralgia
Detailed Description:	

Conditions

Conditions:	Neuralgia
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 2
Intervention Model:	Crossover Assignment
Number of Arms:	2
Masking:	Double Blind (Subject, Investigator, Outcomes Assessor)
Allocation:	Randomized
Endpoint Classification:	Safety/Efficacy Study
Enrollment:	9 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: AGN201781 AGN201781 50 mg capsules three-time daily for 2 weeks	Drug: AGN201781 AGN201781 50 mg capsules three-times daily for 2 weeks
Placebo Comparator: Placebo placebo 50 mg capsules three-times daily for 2 weeks	Drug: placebo placebo 50 mg capsules three-times daily for 2 weeks

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years

Maximum Age: 80 Years

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- Diagnosis of postherpetic neuralgia or post-traumatic peripheral neuralgia
- Moderate or severe pain associated with postherpetic neuralgia or post-traumatic peripheral neuralgia

Exclusion Criteria:

- Women of child-bearing potential
- Any other uncontrolled diseases

Contacts/Locations

Study Officials: Medical Director
Study Director
Allergan

Locations: Germany
Kiel, Germany

Australia, New South Wales
St. Leonards, New South Wales, Australia

References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Pre-Assignment Details	There were 2 Treatment Periods in this Cross-Over Study. Patients randomized to AGN201781 during Period 1 received Placebo during Period 2. Patients randomized to Placebo during Period 1 received AGN201781 during Period 2. Period 3 was an Observational Period only (No treatment provided).

Reporting Groups

	Description
AGN201781 Followed by Placebo	
Placebo Followed by AGN201781	

Period 1

	AGN201781 Followed by Placebo	Placebo Followed by AGN201781
Started	7	2
Completed	5	1
Not Completed	2	1

Period 2

	AGN201781 Followed by Placebo	Placebo Followed by AGN201781
Started	5	1
Completed	5	1
Not Completed	0	0

Period 3

	AGN201781 Followed by Placebo	Placebo Followed by AGN201781
Started	3 [1]	0 [2]
Completed	3	0
Not Completed	0	0

[1] Three out of the five patients who completed Period 2 continued to Period 3
[2] No patients continued to Period 3

Baseline Characteristics

Reporting Groups

	Description
AGN201781 Followed by Placebo	
Placebo Followed by AGN201781	

Baseline Measures

	AGN201781 Followed by Placebo	Placebo Followed by AGN201781	Total
Number of Participants	7	2	9
Age, Continuous [units: years] Mean (Standard Deviation)	60.6 (11.01)	49 (36.77)	54.8 (23.89)
Gender, Male/Female [units: participants]			
Female	5	0	5
Male	2	2	4

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Change From Baseline in Daily Pain Score at Week 2
Measure Description	Change from baseline in the daily-average-pain score at week 2. This was measured using a 11-point (0 to 10) scale where 0 represented no pain and 10 represented worst pain. Due to the low number of patients completing the treatment period of the study no analyses were performed

Time Frame	Baseline, Week 2
Safety Issue?	No

Analysis Population Description

Due to low number of patients completing the treatment period of the study no analyses were performed

Reporting Groups

	Description
AGN201781	
Placebo	

Measured Values

	AGN201781	Placebo
Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

2. Secondary Outcome Measure:

Measure Title	Change From Baseline in Subject Global Impression of Change Score at Week 2
Measure Description	Change from baseline in Subject Global Impression of Change score at week 2. The Subject Global Impression of Change is a self-evaluation by the subject of their overall change in relief of neuropathic pain since the beginning of the study rated on a 7-point scale (1=very much improved to 7=very much worse). Due to low number of patients completing the treatment period of the study no analyses were performed.
Time Frame	Baseline, Week 2
Safety Issue?	No

Analysis Population Description

Due to low number of patients completing the treatment period of the study no analyses were performed.

Reporting Groups

	Description
AGN201781	
Placebo	

Measured Values

	AGN201781	Placebo
Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

Reported Adverse Events

Time Frame	[Not specified]
Additional Description	[Not specified]

Reporting Groups

	Description
AGN201781 Followed by Placebo	
Placebo Followed by AGN201781	

Serious Adverse Events

	AGN201781 Followed by Placebo	Placebo Followed by AGN201781
	Affected/At Risk (%)	Affected/At Risk (%)
Total	0/7 (0%)	0/2 (0%)

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	AGN201781 Followed by Placebo	Placebo Followed by AGN201781
	Affected/At Risk (%)	Affected/At Risk (%)
Total	4/7 (57.14%)	1/2 (50%)
Endocrine disorders		
Hypothyroidism [A] †	1/7 (14.29%)	0/2 (0%)
General disorders		
Fatigue [A] *	1/7 (14.29%)	0/2 (0%)
Investigations		

	AGN201781 Followed by Placebo	Placebo Followed by AGN201781
	Affected/At Risk (%)	Affected/At Risk (%)
Alanine aminotransferase increased [A] †	1/7 (14.29%)	0/2 (0%)
Blood creatinine increased [A] †	1/7 (14.29%)	0/2 (0%)
Nervous system disorders		
Headache [A] *	1/7 (14.29%)	0/2 (0%)
Somnolence [A] *	0/7 (0%)	1/2 (50%)
Renal and urinary disorders		
Leukocyturia [A] †	0/7 (0%)	1/2 (50%)
Renal pain [A] [1] *	0/7 (0%)	1/2 (50%)
Respiratory, thoracic and mediastinal disorders		
Dyspnoea [A] *	0/7 (0%)	1/2 (50%)
Skin and subcutaneous tissue disorders		
Pityriasis rosea [A] *	0/7 (0%)	1/2 (50%)
Vascular disorders		
Hypertension [A] †	1/7 (14.29%)	0/2 (0%)

† Indicates events were collected by systematic assessment.
* Indicates events were collected by non-systematic methods.
A Term from vocabulary, MedDRA (10.0)

[1] Event occurred during Period 3 (Observational/No Treatment)

Limitations and Caveats

This study was terminated early due to low enrollment (only 9 of the required 40 subjects had been enrolled). Due to the low number of patients who completed the treatment period of the study, no analyses were performed.

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

A disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is less than or equal to 40 days from the time submitted to the sponsor for review. The sponsor cannot require changes to the communication and cannot extend the embargo

Results Point of Contact:

Name/Official Title: Therapeutic Area Head
Organization: Allergan, Inc.
Phone: 714-246-4500
Email: clinicaltrials@allergan.com