ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 10/10/2012

ClinicalTrials.gov ID: NCT01019928

Study Identification

Unique Protocol ID:	D9127C00002
Brief Title:	Esophageal Hypersensitivity Study in Patients With Gastroesophageal Reflux Disease (GERD)
Official Title:	A Phase IIa, Double-blind, Randomized, 2-way Cross-over Study to Evaluate the Effect of a Single Dose of AZD1386 95 mg Compared to Placebo in a Multimodal Experimental Pain Model on Esophageal Sensitivity in GERD Patients With a Partial Response to PPI Treatment
Secondary IDs:	2008-007420-26

Study Status

Record Verification:	October 2012
Overall Status:	Completed
Study Start:	November 2009
Primary Completion:	January 2011 [Actual]
Study Completion:	January 2011 [Actual]

Sponsor/Collaborators

Sponsor:	AstraZeneca
Responsible Party:	Sponsor
Collaborators:	

Oversight

FDA Regulated?:	No

IND/IDE Protocol?:	No
Review Board:	Approval Status: Approved Approval Number: 214-09 Board Name: Regionala etikprövningsnämnden i Göteborg, Sweden Board Affiliation: Regionala etikprövningsnämnden i Göteborg, Sweden Phone: +46 31 786 68 21 Email:
Data Monitoring?:	No
Plan to Share Data?:	
Oversight Authorities:	Denmark: Danish Medicines Agency Sweden: Medical Products Agency

Study Description

Brief Summary:	The purpose of the study is to compare sensitivity of visceral pain in the esophagus using different pain stimuli.
Detailed Description:	

Conditions

Conditions:	Sensitivity in Esophagus
Keywords:	GERD patient esophagus pain

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 2
Intervention Model:	Crossover Assignment
Number of Arms:	2
Masking:	Double Blind (Subject, Caregiver, Investigator)
Allocation:	Randomized
Endpoint Classification:	Efficacy Study

Enrollment: 14 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: First AZD1386, then washout, then placebo	Drug: AZD1386 95 mg, oral solution, single dose Drug: Placebo to AZD1386 Placebo, oral solution, single dose
Experimental: First placebo, then washout, then AZD1386	Drug: AZD1386 95 mg, oral solution, single dose Drug: Placebo to AZD1386 Placebo, oral solution, single dose

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years

Maximum Age: 70 Years

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- Provision of signed informed consent form
- BMI 18.5-35.0, inclusive
- Continuous PPI treatment for GERD during the last 4 weeks

Exclusion Criteria:

- Patients that have not experienced any GERD symptoms improvement at all after PPI treatment
- Unstable or clinically significant disorders including cardiovascular, respiratory, renal, hepatic, metabolic, psychiatric, other gastrointestinal and esophageal disorders besides GERD
- Prior surgery of the upper GI tract

Contacts/Locations

Study Officials: Marie Sundin
Study Director

AstraZeneca R&D Mölndal, Sweden

Peter Funch-Jensen,, MD, PhD
Study Principal Investigator
Aarhus Hospital, Dept of Surgical Gastroenterology, Aarhus, Denmark

Locations: Sweden
Research Site
Goteborg, Vastra Gotaland, Sweden

Denmark
Research Site
Århus C, Denmark

References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Recruitment Details	A total of 30 patients were enrolled, 16 of these patients were NOT randomized for the following reasons: Voluntary discontinuation by patient = 3 Incorrect enrollment (did not meet inclusion/excl criteria) = 13
Pre-Assignment Details	14 patients were randomised, 1 patient received placebo in the first treatment period without any events, but had an SAE prior to receiving AZD1386 in the second period and was withdrawn. 13 randomised patients completed the study, but one of these patients was incorrectly enrolled and excluded from the per-protocol analysis set.

Reporting Groups

	Description
First AZD1386, Then Washout, Then Placebo	

	Description
First Placebo, Then Washout, Then AZD1386	

Period 1

	First AZD1386, Then Washout, Then Placebo	First Placebo, Then Washout, Then AZD1386
Started	7	7
Completed	7	7
Not Completed	0	0

Period 2

	First AZD1386, Then Washout, Then Placebo	First Placebo, Then Washout, Then AZD1386
Started	7	7
Completed	7	6 [1]
Not Completed	0	1

[1] One patient had an SAE, and was withdrawn, prior to receiving AZD1386

Period 3

	First AZD1386, Then Washout, Then Placebo	First Placebo, Then Washout, Then AZD1386
Started	7	6 [1]
Completed	7	6 [1]
Not Completed	0	0

[1] One patient had an SAE, and was withdrawn, prior to receiving AZD1386

Baseline Characteristics

Reporting Groups

	Description
AZD1386 95 mg	
Placebo	

Baseline Measures

	AZD1386 95 mg	Placebo	Total
Number of Participants	7	7	14
Age, Continuous Age (years) [units: years] Mean (Standard Deviation)	54.9 (15.0)	54.7 (17.4)	54.8 (16.2)
Gender, Male/Female [units: Participants]			
Female	5	4	9
Male	2	3	5

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Time to Visual Analogue Scale 7 (VAS7) During Thermal Stimulation at 1.5 Hours Post-Dose.
Measure Description	A probe (bag) was inserted 7cm above the lower esophageal sphincter (LES). Heat stimuli were applied by recirculation of heated water in the bag. Prior to recirculation the bag is filled with 7mL to ensure adequate mucosal contact. Water was heated up to a maximum of 63° C and the stimulation was continued until VAS 7 was reached. The intensities of the non-painful sensations were scored with the following descriptors added to facilitate the scoring: 1. = vague perception of mild sensation 2. = definite perception of mild sensation 3. = vague perception of moderate sensation 4. = definite perception of moderate sensation For painful sensations the patients will use the scale from 5-10 anchored at: 5. = pain detection 6. = slight pain 7. = moderate pain 8. = medium pain intensity 9. = intense pain 10. = unbearable pain
Time Frame	1.5 hours post dose
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
AZD1386 95 mg	
Placebo	

Measured Values

	AZD1386 95 mg	Placebo
Number of Participants Analyzed	12	13
Time to Visual Analogue Scale 7 (VAS7) During Thermal Stimulation at 1.5 Hours Post-Dose. [units: seconds] Geometric Mean (Full Range)	84.0 (36 to 146)	86.9 (29 to 127)

2. Secondary Outcome Measure:

Measure Title	Time to Visual Analogue Scale 7 (VAS7) During Thermal Stimulation at 0.5 Hours Post Dose
Measure Description	A probe (bag) was inserted 7cm above the lower esophageal sphincter (LES). Heat stimuli were applied by recirculation of heated water in the bag. Prior to recirculation the bag is filled with 7mL to ensure adequate mucosal contact. Water was heated up to a maximum of 63° C and the stimulation was continued until VAS 7 was reached. The intensities of the non-painful sensations were scored with the following descriptors added to facilitate the scoring: 1. = vague perception of mild sensation 2. = definite perception of mild sensation 3. = vague perception of moderate sensation 4. = definite perception of moderate sensation For painful sensations the patients will use the scale from 5-10 anchored at: 5. = pain detection 6. = slight pain 7. = moderate pain 8. = medium pain intensity 9. = intense pain 10. = unbearable pain
Time Frame	0.5 hours post dose
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
AZD1386 95 mg	
Placebo	

Measured Values

	AZD1386 95 mg	Placebo
Number of Participants Analyzed	12	13
Time to Visual Analogue Scale 7 (VAS7) During Thermal Stimulation at 0.5 Hours Post Dose [units: seconds] Geometric Mean (Full Range)	86.0 (41 to 157)	87.8 (31 to 132)

3. Secondary Outcome Measure:

Measure Title	Time to Visual Analogue Scale 7 (VAS7) During Thermal Stimulation at 2.5 Hours Post Dose
Measure Description	A probe (bag) was inserted 7cm above the lower esophageal sphincter (LES). Heat stimuli were applied by recirculation of heated water in the bag. Prior to recirculation the bag is filled with 7mL to ensure adequate mucosal contact. Water was heated up to a maximum of 63° C and the stimulation was continued until VAS 7 was reached. The intensities of the non-painful sensations were scored with the following descriptors added to facilitate the scoring: 1. = vague perception of mild sensation 2. = definite perception of mild sensation 3. = vague perception of moderate sensation 4. = definite perception of moderate sensation For painful sensations the patients will use the scale from 5-10 anchored at: 5. = pain detection 6. = slight pain 7. = moderate pain 8. = medium pain intensity 9. = intense pain 10. = unbearable pain
Time Frame	2.5 hours post dose
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
AZD1386 95 mg	
Placebo	

Measured Values

	AZD1386 95 mg	Placebo
Number of Participants Analyzed	12	13
Time to Visual Analogue Scale 7 (VAS7) During Thermal Stimulation at 2.5 Hours Post Dose [units: seconds] Geometric Mean (Full Range)	85.5 (39 to 150)	77.0 (24 to 125)

4. Secondary Outcome Measure:

Measure Title	Volume at Visual Analogue Scale 7 (VAS7) During Mechanical Stimulation at 0.5 Hours Post Dose
Measure Description	A probe (bag) was inserted 7cm above the lower esophageal sphincter (LES). Volume change in the bag was recorded continuously at each level of the visual analogue scale (VAS) and up to VAS7 (Volume at Visual Analogue Scale 7). The intensities of the non-painful sensations were scored with the following descriptors added to facilitate the scoring: 1. = vague perception of mild sensation 2. = definite perception of mild sensation 3. = vague perception of moderate sensation 4. = definite perception of moderate sensation For painful sensations the patients will use the scale from 5-10 anchored at: 5. = pain detection 6. = slight pain 7. = moderate pain 8. = medium pain intensity 9. = intense pain 10. = unbearable pain
Time Frame	0.5 hours post dose
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
AZD1386 95 mg	
Placebo	

Measured Values

	AZD1386 95 mg	Placebo
Number of Participants Analyzed	12	13
Volume at Visual Analogue Scale 7 (VAS7) During Mechanical Stimulation at 0.5 Hours Post Dose [units: ml] Geometric Mean (Full Range)	16.2 (8 to 37)	15.1 (6 to 41)

5. Secondary Outcome Measure:

Measure Title	Volume at Visual Analogue Scale 7 (VAS7) During Mechanical Stimulation at 1.5 Hours Post-Dose
Measure Description	A probe (bag) was inserted 7cm above the lower esophageal sphincter (LES). Volume change in the bag was recorded continuously at each level of the visual analogue scale (VAS) and up to VAS7 (Volume at Visual Analogue Scale 7). The intensities of the non-painful sensations were scored with the following descriptors added to facilitate the scoring: 1. = vague perception of mild sensation 2. = definite perception of mild sensation 3. = vague perception of moderate sensation 4. = definite perception of moderate sensation For painful sensations the patients will use the scale from 5-10 anchored at: 5. = pain detection 6. = slight pain 7. = moderate pain 8. = medium pain intensity 9. = intense pain 10. = unbearable pain
Time Frame	1.5 hours post dose
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
AZD1386 95 mg	
Placebo	

Measured Values

	AZD1386 95 mg	Placebo
Number of Participants Analyzed	12	13
Volume at Visual Analogue Scale 7 (VAS7) During Mechanical Stimulation at 1.5 Hours Post-Dose [units: ml] Geometric Mean (Full Range)	15.0 (8 to 24)	16.7 (8 to 30)

6. Secondary Outcome Measure:

Measure Title	Volume at Visual Analogue Scale 7 (VAS7) During Mechanical Stimulation at 2.5 Hours Post-Dose.
Measure Description	A probe (bag) was inserted 7cm above the lower esophageal sphincter (LES). Volume change in the bag was recorded continuously at each level of the visual analogue scale (VAS) and up to VAS7 (Volume at Visual Analogue Scale 7). The intensities of the non-painful sensations were scored with the following descriptors added to facilitate the scoring: 1. = vague perception of mild sensation 2. = definite perception of mild sensation 3. = vague perception of moderate sensation 4. = definite perception of moderate sensation For painful sensations the patients will use the scale from 5-10 anchored at: 5. = pain detection 6. = slight pain 7. = moderate pain 8. = medium pain intensity 9. = intense pain 10. = unbearable pain
Time Frame	2.5 hours post dose
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
AZD1386 95 mg	
Placebo	

Measured Values

	AZD1386 95 mg	Placebo
Number of Participants Analyzed	11	13
Volume at Visual Analogue Scale 7 (VAS7) During Mechanical Stimulation at 2.5 Hours Post-Dose. [units: ml] Geometric Mean (Full Range)	15.4 (6 to 29)	15.2 (5 to 38)

7. Secondary Outcome Measure:

Measure Title	Current at Visual Analogue Scale 7 (VAS7) During Electrical Stimulation 0.5 Hours Post Dose
Measure Description	A probe (bag) was inserted 7cm above the lower esophageal sphincter (LES) and stimulations were performed at approximately 8 cm above the LES. The intensity of the stimuli is increased steadily in steps of 0.5 to 1 mA and the intensity corresponding to the VAS levels 1, 3, 5 and 7 were recorded. The current will be increased until the patient report moderate pain (VAS 7) or max 80 mA. The intensities of the non-painful sensations were scored with the following descriptors added to facilitate the scoring: 1. = vague perception of mild sensation 2. = definite perception of mild sensation 3. = vague perception of moderate sensation 4. = definite perception of moderate sensation For painful sensations the patients will use the scale from 5-10 anchored at: 5. = pain detection 6. = slight pain 7. = moderate pain 8. = medium pain intensity 9. = intense pain 10. = unbearable pain
Time Frame	0.5 hours post dose

Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
AZD1386 95 mg	
Placebo	

Measured Values

	AZD1386 95 mg	Placebo
Number of Participants Analyzed	12	12
Current at Visual Analogue Scale 7 (VAS7) During Electrical Stimulation 0.5 Hours Post Dose [units: mA] Geometric Mean (Full Range)	16.7 (9 to 31)	16.7 (9 to 40)

8. Secondary Outcome Measure:

Measure Title	Current at Visual Analogue Scale 7 (VAS7) During Electrical Stimulation at 1.5 Hours Post Dose

Measure Description	A probe (bag) was inserted 7cm above the lower esophageal sphincter (LES) and stimulations were performed at approximately 8 cm above the LES. The intensity of the stimuli is increased steadily in steps of 0.5 to 1 mA and the intensity corresponding to the VAS levels 1, 3, 5 and 7 were recorded. The current will be increased until the patient report moderate pain (VAS 7) or max 80 mA. The intensities of the non-painful sensations were scored with the following descriptors added to facilitate the scoring: 1. = vague perception of mild sensation 2. = definite perception of mild sensation 3. = vague perception of moderate sensation 4. = definite perception of moderate sensation For painful sensations the patients will use the scale from 5-10 anchored at: 5. = pain detection 6. = slight pain 7. = moderate pain 8. = medium pain intensity 9. = intense pain 10. = unbearable pain
Time Frame	1.5 hours post dose
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
AZD1386 95 mg	
Placebo	

Measured Values

	AZD1386 95 mg	Placebo
Number of Participants Analyzed	12	12
Current at Visual Analogue Scale 7 (VAS7) During Electrical Stimulation at 1.5 Hours Post Dose [units: mA] Geometric Mean (Full Range)	16.7 (8 to 30)	15.8 (8 to 37)

9. Secondary Outcome Measure:

Measure Title	Current at Visual Analogue Scale 7 (VAS7) During Electrical Stimulation at 2.5 Hours Post Dose
Measure Description	A probe (bag) was inserted 7cm above the lower esophageal sphincter (LES) and stimulations were performed at approximately 8 cm above the LES. The intensity of the stimuli is increased steadily in steps of 0.5 to 1 mA and the intensity corresponding to the VAS levels 1, 3, 5 and 7 were recorded. The current will be increased until the patient report moderate pain (VAS 7) or max 80 mA. The intensities of the non-painful sensations were scored with the following descriptors added to facilitate the scoring: 1. = vague perception of mild sensation 2. = definite perception of mild sensation 3. = vague perception of moderate sensation 4. = definite perception of moderate sensation For painful sensations the patients will use the scale from 5-10 anchored at: 5. = pain detection 6. = slight pain 7. = moderate pain 8. = medium pain intensity 9. = intense pain 10. = unbearable pain
Time Frame	2.5 hours post dose
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
AZD1386 95 mg	
Placebo	

Measured Values

	AZD1386 95 mg	Placebo
Number of Participants Analyzed	11	12
Current at Visual Analogue Scale 7 (VAS7) During Electrical Stimulation at 2.5 Hours Post Dose [units: mA] Geometric Mean (Full Range)	16.2 (8 to 31)	14.8 (8 to 28)

10. Secondary Outcome Measure:

Measure Title	AUCt
Measure Description	Area under the plasma concentration curve from time zero to the last quantifiable concentration
Time Frame	0 to 4 hours post dose
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
AZD1386 95 mg	
Placebo	

Measured Values

	AZD1386 95 mg	Placebo
Number of Participants Analyzed	12	0
AUCt [units: nmol*h/L] Geometric Mean (95% Confidence Interval)	5899 (4735 to 7349)	

11. Secondary Outcome Measure:

Measure Title	Cmax
Measure Description	Maximum plasma concentration
Time Frame	0 to 4 hours post dose
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
AZD1386 95 mg	
Placebo	

Measured Values

	AZD1386 95 mg	Placebo
Number of Participants Analyzed	12	0
Cmax [units: nmol/L] Geometric Mean (95% Confidence Interval)	2361 (1859 to 3000)	

12. Secondary Outcome Measure:

Measure Title	Tmax
Measure Description	Time of maximum plasma concentration
Time Frame	0 to 4 hours post dose
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
AZD1386 95 mg	
Placebo	

Measured Values

	AZD1386 95 mg	Placebo
Number of Participants Analyzed	12	0
Tmax [units: hours] Median (Full Range)	1.0 (0.5 to 2.5)	

13. Secondary Outcome Measure:

Measure Title	SBP
Measure Description	Supine Systolic Blood Pressure at 1.5 hours post dose
Time Frame	1.5 hours post dose
Safety Issue?	Yes

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
AZD1386 95 mg	
Placebo	

Measured Values

	AZD1386 95 mg	Placebo
Number of Participants Analyzed	13	14
SBP [units: mmHg] Mean (Standard Deviation)	145.8 (10.3)	139.7 (12.7)

14. Secondary Outcome Measure:

Measure Title	DBP
Measure Description	Supine Diastolic Blood Pressure at 1.5 hours post dose
Time Frame	1.5 hours post dose
Safety Issue?	Yes

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
AZD1386 95 mg	
Placebo	

Measured Values

	AZD1386 95 mg	Placebo
Number of Participants Analyzed	13	14
DBP [units: mmHg] Mean (Standard Deviation)	81.4 (8.1)	80.0 (7.3)

15. Secondary Outcome Measure:

Measure Title	Pulse
Measure Description	Supine Pulse at 1.5 hours post dose
Time Frame	1.5 hours post dose
Safety Issue?	Yes

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
AZD1386 95 mg	
Placebo	

Measured Values

	AZD1386 95 mg	Placebo
Number of Participants Analyzed	13	14
Pulse [units: beats/min] Mean (Standard Deviation)	67.8 (12.9)	62.2 (9.4)

16. Secondary Outcome Measure:

Measure Title	QTcF
Measure Description	QT interval corrected for heart rate using Fredericia formula(QTcF) at 1.5 hours post dose
Time Frame	1.5 hours post dose
Safety Issue?	Yes

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
AZD1386 95 mg	
Placebo	

Measured Values

	AZD1386 95 mg	Placebo
Number of Participants Analyzed	13	14
QTcF [units: ms] Mean (Standard Deviation)	409.6 (19.0)	414.3 (17.3)

17. Secondary Outcome Measure:

Measure Title	Body Temperature
Measure Description	Oral Body Temperature at 1.5 hours post dose
Time Frame	1.5 hours post dose
Safety Issue?	Yes

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
AZD1386 95 mg	
Placebo	

Measured Values

	AZD1386 95 mg	Placebo
Number of Participants Analyzed	13	14
Body Temperature [units: degrees Celsius] Mean (Standard Deviation)	37.2 (0.4)	36.8 (0.3)

18. Secondary Outcome Measure:

Measure Title	Clinically Relevant Change of Laboratory Variables
Measure Description	Number of participants with clinically relevant change of laboratory variables(clinical chemistry, haematology and urinalysis parameters)
Time Frame	Pre-entry to follow-up
Safety Issue?	Yes

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
AZD1386 95 mg	
Placebo	

Measured Values

	AZD1386 95 mg	Placebo
Number of Participants Analyzed	13	14
Clinically Relevant Change of Laboratory Variables [units: Participants]	0	0

Reported Adverse Events

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

Reporting Groups

	Description
AZD1386 95 mg	
Placebo	

Serious Adverse Events

	AZD1386 95 mg	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)
Total	0/13 (0%)	1/14 (7.14%)
Cardiac disorders		
ECG, atrial fibrillation [A]	0/13 (0%)	1/14 (7.14%)

A Term from vocabulary, MedDRA 10.0

Other Adverse Events

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

	AZD1386 95 mg	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)
Total	11/13 (84.62%)	2/14 (14.29%)
Gastrointestinal disorders		
Dyspepsia [A]	0/13 (0%)	1/14 (7.14%)
Nausea [A]	1/13 (7.69%)	0/14 (0%)
Oesophageal Disorder [A]	1/13 (7.69%)	0/14 (0%)
Vomiting [A]	1/13 (7.69%)	0/14 (0%)

	AZD1386 95 mg	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)
General disorders		
Chills [A]	1/13 (7.69%)	0/14 (0%)
Feeling Cold [A]	7/13 (53.85%)	0/14 (0%)
Feeling Of Body Temperature Change [A]	1/13 (7.69%)	0/14 (0%)
Hypoaesthesia Oral [A]	3/13 (23.08%)	0/14 (0%)
Pain [A]	0/13 (0%)	1/14 (7.14%)
Peripheral Coldness [A]	1/13 (7.69%)	0/14 (0%)
Injury, poisoning and procedural complications		
Arthropod Sting [A]	1/13 (7.69%)	0/14 (0%)
Investigations		
Body Temperature Increased [A]	4/13 (30.77%)	0/14 (0%)
Musculoskeletal and connective tissue disorders		
Musculoskeletal Chest Pain [A]	1/13 (7.69%)	0/14 (0%)
Nervous system disorders		
Ageusia [A]	1/13 (7.69%)	0/14 (0%)
Burning Sensation [A]	1/13 (7.69%)	0/14 (0%)
Dysgeusia [A]	1/13 (7.69%)	0/14 (0%)
Headache [A]	1/13 (7.69%)	0/14 (0%)
Paraesthesia [A]	1/13 (7.69%)	0/14 (0%)
Respiratory, thoracic and mediastinal disorders		
Throat Irritation [A]	2/13 (15.38%)	0/14 (0%)

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Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

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

The only 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 more than 60 days but less than or equal to 180 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:

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