ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 11/14/2012

ClinicalTrials.gov ID: NCT00444275

Study Identification

Unique Protocol ID:	D9612L00111
Brief Title:	Nexium (Esomeprazole) in Symptom Adapted Therapy in GERD Patients (MAESTRO)
Official Title:	A Randomized, Open, Parallel-group Study to Evaluate the Efficacy of Three Different Patient Management Strategies During a 12 Weeks Maintenance Phase Following an Initial 4-weeks Acute Treatment Phase in Subjects With Symptoms Thought to be GERD Related
Secondary IDs:	EudraCT No: 2006-002867-19

Study Status

Record Verification:	November 2012
Overall Status:	Completed
Study Start:	March 2007
Primary Completion:	October 2008 [Actual]
Study Completion:	October 2008 [Actual]

Sponsor/Collaborators

Sponsor:	AstraZeneca
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: CPP-2006/003 Board Name: CPP Nord-Ouest Board Affiliation: DGS Phone: +33 2 32 88 84 46 Email: CPP.NordOuest@achu-rouen.fr
Data Monitoring?:	No
Plan to Share Data?:	
Oversight Authorities:	France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis)

Study Description

Brief Summary:	To compare the efficacy of three different long-term treatment strategies of reflux disease in primary care setting.
Detailed Description:	

Conditions

Conditions:	GERD
Keywords:	Gastroesophageal Reflux Disease Acid Reflux

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 4
Intervention Model:	Parallel Assignment
Number of Arms:	5
Masking:	Open Label
Allocation:	Randomized
Endpoint Classification:	Efficacy Study

Enrollment: 3029 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Esomeprazole 20 mg Once Daily (initial phase)	Drug: esomeprazole (Nexium®) This randomized study was conducted on parallel groups and included two phases: - One initial phase during when the patients received once daily, either esomeprazole 20 mg or esomeprazole 40 mg, depending on the investigator's decision - One maintenance treatment phase, patients were randomized to one of the following three groups, either esomeprazole 20 mg once daily, or esomeprazole 20 mg on demand or antacid treatment as needed
Experimental: Esomeprazole 40 mg Once Daily (initial phase)	Drug: esomeprazole (Nexium®) This randomized study was conducted on parallel groups and included two phases: - One initial phase during when the patients received once daily, either esomeprazole 20 mg or esomeprazole 40 mg, depending on the investigator's decision - One maintenance treatment phase, patients were randomized to one of the following three groups, either esomeprazole 20 mg once daily, or esomeprazole 20 mg on demand or antacid treatment as needed
Experimental: Esomeprazole 20 mg Once Daily (Maintenance Phase)	Drug: esomeprazole (Nexium®) This randomized study was conducted on parallel groups and included two phases: - One initial phase during when the patients received once daily, either esomeprazole 20 mg or esomeprazole 40 mg, depending on the investigator's decision - One maintenance treatment phase, patients were randomized to one of the following three groups, either esomeprazole 20 mg once daily, or esomeprazole 20 mg on demand or antacid treatment as needed
Experimental: Esomeprazole 20 mg on Demand (Maintenance Phase)	Drug: esomeprazole (Nexium®) This randomized study was conducted on parallel groups and included two phases: - One initial phase during when the patients received once daily, either esomeprazole 20 mg or esomeprazole 40 mg, depending on the investigator's decision - One maintenance treatment phase, patients were randomized to one of the following three groups, either esomeprazole 20 mg once daily, or esomeprazole 20 mg on demand or antacid treatment as needed
Experimental: Antacid Treatment (Maintenance Phase)	Drug: Xolaam® This randomized study was conducted on parallel groups and included two phases: - One initial phase during when the patients received once daily, either esomeprazole 20 mg or esomeprazole 40 mg, depending on the investigator's decision - One maintenance treatment phase, patients were randomized to one of the following three groups, either esomeprazole 20

Arms	Assigned Interventions
	mg once daily, or esomeprazole 20 mg on demand or antacid treatment as needed

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years

Maximum Age: 50 Years

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- Subjects who seek medical advice in primary care for symptoms thought to be GERD related (GERD is a condition which develops when the reflux of stomach content causes troublesome symptoms and / or complications).

Exclusion Criteria:

- Subjects with any clinical GERD treatment (PPI, H2-receptor antagonists) within the last 3 months prior to Visit 1.
- A history of severe esophagitis or known other complications, with alarm symptoms

Contacts/Locations

Study Officials: AstraZeneca France Medical Director, MD
Study Director
AstraZeneca

Locations: France
Research Site
Rouen, France

References

Citations:

Links: URL: http://www.astrazeneca.com/node/emailtriage.aspx
Description AstraZeneca Clinical Trial Information - Outside US

Study Data/Documents:

Study Results

Participant Flow

Recruitment Details	Patients were recruited by general practitioner between March 1, 2007 and July 21, 2008
Pre-Assignment Details	The study included 2 phases (maximum treatment duration = 16 weeks): • one initial treatment phase of 4 weeks • one randomized maintenance treatment phase of 12 weeks only for patients whose initial treatment is considered to be successful at the end of the initial phase. Only maintenance phase data were reported in the Baseline module measures.

Reporting Groups

	Description
Esomeprazole 20 mg Once Daily (Initial Phase)	
Esomeprazole 40 mg Once Daily (Initial Phase)	
Esomeprazole 20 mg Once Daily (Maintenance Phase)	
Esomeprazole 20 mg on Demand (Maintenance Phase)	
Antacid Treatment (Maintenance Phase)	antacid treatment as needed (maintenance phase) (Xolaam® maximum six tablets per day)

Initial Treatment Phase

	Esomeprazole 20 mg Once Daily (Initial Phase)	Esomeprazole 40 mg Once Daily (Initial Phase)	Esomeprazole 20 mg Once Daily (Maintenance Phase)	Esomeprazole 20 mg on Demand (Maintenance Phase)	Antacid Treatment (Maintenance Phase)
Started	2156	873	0	0	0
Completed	1908	777	0	0	0

	Esomeprazole 20 mg Once Daily (Initial Phase)	Esomeprazole 40 mg Once Daily (Initial Phase)	Esomeprazole 20 mg Once Daily (Maintenance Phase)	Esomeprazole 20 mg on Demand (Maintenance Phase)	Antacid Treatment (Maintenance Phase)
Not Completed	248	96	0	0	0

Maintenance Treatment Phase

	Esomeprazole 20 mg Once Daily (Initial Phase)	Esomeprazole 40 mg Once Daily (Initial Phase)	Esomeprazole 20 mg Once Daily (Maintenance Phase)	Esomeprazole 20 mg on Demand (Maintenance Phase)	Antacid Treatment (Maintenance Phase)
Started	0	0	908	897	880
Completed	0	0	747	764	701
Not Completed	0	0	161	133	179
Didn'r receive the treatment	0	0	22	17	29
Lost to Follow-up	0	0	8	14	10
Adverse Event	0	0	3	2	13
Protocol specific criteria's development	0	0	1	0	6
Patient's wish	0	0	19	9	20
Protocol Violation	0	0	103	88	87
Ineffectiveness	0	0	5	3	14

Baseline Characteristics

Reporting Groups

	Description
Esomeprazole 20 mg Once Daily (Maintenance Phase)	
Esomeprazole 20 mg on Demand (Maintenance Phase)	
Antacid Treatment (Maintenance Phase)	antacid treatment as needed (maintenance phase) (Xolaam® maximum six tablets per day)

Baseline Measures

	Esomeprazole 20 mg Once Daily (Maintenance Phase)	Esomeprazole 20 mg on Demand (Maintenance Phase)	Antacid Treatment (Maintenance Phase)	Total
Number of Participants	871	857	830	2558
Age, Continuous [units: years] Mean (Standard Deviation)	41.5 (9.83)	41.79 (9.97)	41.6 (10)	41.64 (9.91)
Gender, Male/Female [units: Participants]				
Female	449	415	411	1275
Male	422	442	419	1283

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Efficacy of Three Strategies of Long-term Treatment
Measure Description	Percentage of failure of maintenance treatment between V2 (4 weeks) and V3 (16 weeks) evaluated by the patient, defined based on responses to 2 questions (if at least 1 negative response was given, the patient was considered to be in failure) : Did the treatment produce sufficient control of reflux symptoms? Do you wish to continue the treatment?
Time Frame	16 weeks
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
Esomeprazole 20 mg Once Daily (Maintenance Phase)	
Esomeprazole 20 mg on Demand (Maintenance Phase)	
Antacid Treatment (Maintenance Phase)	antacid treatment as needed (maintenance phase) (Xolaam® maximum six tablets per day)

Measured Values

	Esomeprazole 20 mg Once Daily (Maintenance Phase)	Esomeprazole 20 mg on Demand (Maintenance Phase)	Antacid Treatment (Maintenance Phase)
Number of Participants Analyzed	871	857	830
Efficacy of Three Strategies of Long-term Treatment [units: Percentage of participants with failure]	10.6	7.8	43

2. Secondary Outcome Measure:

Measure Title	Difference in Symptom Severity Evaluation Performed by the Investigators, When Symptom Severity is Assessed With and Without Reflux Disease Questionnaire (RDQ).
Measure Description	Total percentage of subjects for whom evaluation of symptom severity using the Reflux Disease Questionnaire (RDQ) is different, either positively or negatively, as compared to clinical judgment made by Investigator. The RDQ Includes 12 Items: 6 Concern the Frequency of Symptoms Ranging From "Never" for the Lowest Frequency to "Every Day" for the Highest, 6 Others Assess the Severity of Symptoms From "Not at All" to "Strong". The Total Score of the RDQ, Ranging From 0 to 40, is Obtained by Adding the Scores of Each Item.
Time Frame	4 weeks
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
Esomeprazole 20 mg Once Daily (Initial Phase)	
Esomeprazole 40 mg Once Daily (Initial Phase)	
Esomeprazole 20 mg Once Daily (Maintenance Phase)	
Esomeprazole 20 mg on Demand (Maintenance Phase)	
Antacid Treatment (Maintenance Phase)	antacid treatment as needed (maintenance phase) (Xolaam® maximum six tablets per day)

Measured Values

	Esomeprazole 20 mg Once Daily (Initial Phase)	Esomeprazole 40 mg Once Daily (Initial Phase)	Esomeprazole 20 mg Once Daily (Maintenance Phase)	Esomeprazole 20 mg on Demand (Maintenance Phase)	Antacid Treatment (Maintenance Phase)
Number of Participants Analyzed	1909	778	0	0	0
Difference in Symptom Severity Evaluation Performed by the Investigators, When Symptom Severity is Assessed With and Without Reflux Disease Questionnaire (RDQ). [units: Percentage of participants]	3.7	2.3			

3. Secondary Outcome Measure:

Measure Title	Impact of Treatment With Low Dose Aspirin (Acetyl Salicylic Acid) Used Concomitantly During the Initial Phase and the Maintenance Phase
Measure Description	No possibility to describe as only 2 patients took ASA
Time Frame	4 weeks
Safety Issue?	No

Analysis Population Description

Outcome measure not possible to describe as only 2 patients took Aspirin.

Reporting Groups

	Description
Esomeprazole 20 mg Once Daily (Initial Phase)	
Esomeprazole 40 mg Once Daily (Initial Phase)	
Esomeprazole 20 mg Once Daily (Maintenance Phase)	
Esomeprazole 20 mg on Demand (Maintenance Phase)	

	Description
Antacid Treatment (Maintenance Phase)	antacid treatment as needed (maintenance phase) (Xolaam® maximum six tablets per day)

Measured Values

	Esomeprazole 20 mg Once Daily (Initial Phase)	Esomeprazole 40 mg Once Daily (Initial Phase)	Esomeprazole 20 mg Once Daily (Maintenance Phase)	Esomeprazole 20 mg on Demand (Maintenance Phase)	Antacid Treatment (Maintenance Phase)
Number of Participants Analyzed	0	0	0	0	0

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

4. Secondary Outcome Measure:

Measure Title	Differences Among Strategies of Maintenance Treatment for Satisfaction of the Patient, Using the GIS (Gord Impact Scale) Scale.(Change in Values of Score Derived From the GIS Questionnaire From V2 to V3 = Start to End of the Maintenance Phase)
Measure Description	Change in values of upper digestive symptoms (GORD Impact Scale) from week 4 to week 16. Scale of 1 to 4 : 1 = every day, 2 = often, 3 = sometime, 4 = never)
Time Frame	4 to 16 weeks
Safety Issue?	No

Analysis Population Description

871 (-66 missing data, 801 (-56 missing data), 833 (-75 missing data)

Reporting Groups

	Description
Esomeprazole 20 mg Once Daily (Initial Phase)	
Esomeprazole 40 mg Once Daily (Initial Phase)	
Esomeprazole 20 mg Once Daily (Maintenance Phase)	
Esomeprazole 20 mg on Demand (Maintenance Phase)	

	Description
Antacid Treatment (Maintenance Phase)	antacid treatment as needed (maintenance phase) (Xolaam® maximum six tablets per day)

Measured Values

	Esomeprazole 20 mg Once Daily (Initial Phase)	Esomeprazole 40 mg Once Daily (Initial Phase)	Esomeprazole 20 mg Once Daily (Maintenance Phase)	Esomeprazole 20 mg on Demand (Maintenance Phase)	Antacid Treatment (Maintenance Phase)
Number of Participants Analyzed	0	0	871	801	833
Differences Among Strategies of Maintenance Treatment for Satisfaction of the Patient, Using the GIS (Gord Impact Scale) Scale.(Change in Values of Score Derived From the GIS Questionnaire From V2 to V3 = Start to End of the Maintenance Phase) [units: Scores on scale] Mean (Standard Deviation)			0.12 (0.79)	0.04 (0.73)	-0.22 (0.8)

5. Secondary Outcome Measure:

Measure Title	Impact of Anxiety and Depression During the Initial Visit Measured by the HADS (Hospital Anxiety and Depression Scale) Questionnaire on Response to Initial Treatment and to Maintenance Treatment
Measure Description	Failure of treatment (as defined as in primary outcome measure) according to confirmed anxiety and depression during maintenance treatment evaluated by the patient via the score of HADS questionnaire. HADS scale ranges= 0 to 21 (the higher score, the worse : ≤7 : no anxiety-depression/ [8-10] : possible anxiety-depression/ >10 : anxiety-depression)
Time Frame	16 weeks
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
Esomeprazole 20 mg Once Daily (Initial Phase)	

	Description
Esomeprazole 40 mg Once Daily (Initial Phase)	
Esomeprazole 20 mg Once Daily (Maintenance Phase)	
Esomeprazole 20 mg on Demand (Maintenance Phase)	
Antacid Treatment (Maintenance Phase)	antacid treatment as needed (maintenance phase) (Xolaam® maximum six tablets per day)

Measured Values

	Esomeprazole 20 mg Once Daily (Initial Phase)	Esomeprazole 40 mg Once Daily (Initial Phase)	Esomeprazole 20 mg Once Daily (Maintenance Phase)	Esomeprazole 20 mg on Demand (Maintenance Phase)	Antacid Treatment (Maintenance Phase)
Number of Participants Analyzed	0	0	871	857	830
Impact of Anxiety and Depression During the Initial Visit Measured by the HADS (Hospital Anxiety and Depression Scale) Questionnaire on Response to Initial Treatment and to Maintenance Treatment [units: Percent of participants with failure]			9.8	9.3	43.7

6. Secondary Outcome Measure:

Measure Title	Number of Participants and Type of Serious Adverse Events and Adverse Events Leading to a Premature Discontinuation of the Study
Measure Description	Number of participants with serious adverse events and adverse events leading to study treatment discontinuation. AE and SAE as defined in ICH-GCP.
Time Frame	12 weeks - maintenance treatment phase
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
Esomeprazole 20 mg Once Daily (Initial Phase)	
Esomeprazole 40 mg Once Daily (Initial Phase)	
Esomeprazole 20 mg Once Daily (Maintenance Phase)	
Esomeprazole 20 mg on Demand (Maintenance Phase)	
Antacid Treatment (Maintenance Phase)	antacid treatment as needed (maintenance phase) (Xolaam® maximum six tablets per day)

Measured Values

	Esomeprazole 20 mg Once Daily (Initial Phase)	Esomeprazole 40 mg Once Daily (Initial Phase)	Esomeprazole 20 mg Once Daily (Maintenance Phase)	Esomeprazole 20 mg on Demand (Maintenance Phase)	Antacid Treatment (Maintenance Phase)
Number of Participants Analyzed	0	0	886	880	851
Number of Participants and Type of Serious Adverse Events and Adverse Events Leading to a Premature Discontinuation of the Study [units: Participants]			5	4	15

7. Secondary Outcome Measure:

Measure Title	Score Abacuses Based on the Reflux Disease Questionnaire (RDQ) Questionnaire
Measure Description	May be used to evaluate the severity of symptoms during the initial visit. Not done
Time Frame	Day 0
Safety Issue?	No

Analysis Population Description

The results of exploratory analyses are not available.

Reporting Groups

	Description
Esomeprazole 20 mg Once Daily (Initial Phase)	
Esomeprazole 40 mg Once Daily (Initial Phase)	
Esomeprazole 20 mg Once Daily (Maintenance Phase)	
Esomeprazole 20 mg on Demand (Maintenance Phase)	
Antacid Treatment (Maintenance Phase)	antacid treatment as needed (maintenance phase) (Xolaam® maximum six tablets per day)

Measured Values

	Esomeprazole 20 mg Once Daily (Initial Phase)	Esomeprazole 40 mg Once Daily (Initial Phase)	Esomeprazole 20 mg Once Daily (Maintenance Phase)	Esomeprazole 20 mg on Demand (Maintenance Phase)	Antacid Treatment (Maintenance Phase)
Number of Participants Analyzed	0	0	0	0	0

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

8. Secondary Outcome Measure:

Measure Title	Score Abacuses Based on the Reflux Disease Questionnaire (RDQ) Questionnaire
Measure Description	May be used to offer patients a strategy of treatment during the initial phase and in the long term. Not done
Time Frame	Day 0
Safety Issue?	No

Analysis Population Description

The results of exploratory analyses are not available.

Reporting Groups

	Description
Esomeprazole 20 mg Once Daily (Initial Phase)	
Esomeprazole 40 mg Once Daily (Initial Phase)	
Esomeprazole 20 mg Once Daily (Maintenance Phase)	
Esomeprazole 20 mg on Demand (Maintenance Phase)	
Antacid Treatment (Maintenance Phase)	antacid treatment as needed (maintenance phase) (Xolaam® maximum six tablets per day)

Measured Values

	Esomeprazole 20 mg Once Daily (Initial Phase)	Esomeprazole 40 mg Once Daily (Initial Phase)	Esomeprazole 20 mg Once Daily (Maintenance Phase)	Esomeprazole 20 mg on Demand (Maintenance Phase)	Antacid Treatment (Maintenance Phase)
Number of Participants Analyzed	0	0	0	0	0

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

9. Secondary Outcome Measure:

Measure Title	Score Abacuses Based on the Reflux Disease Questionnaire (RDQ)
Measure Description	May be used to define the success of treatment. Not done
Time Frame	Week 4
Safety Issue?	No

Analysis Population Description

The results of exploratory analyses are not available.

Reporting Groups

	Description
Esomeprazole 20 mg Once Daily (Initial Phase)	

	Description
Esomeprazole 40 mg Once Daily (Initial Phase)	
Esomeprazole 20 mg Once Daily (Maintenance Phase)	
Esomeprazole 20 mg on Demand (Maintenance Phase)	
Antacid Treatment (Maintenance Phase)	antacid treatment as needed (maintenance phase) (Xolaam® maximum six tablets per day)

Measured Values

	Esomeprazole 20 mg Once Daily (Initial Phase)	Esomeprazole 40 mg Once Daily (Initial Phase)	Esomeprazole 20 mg Once Daily (Maintenance Phase)	Esomeprazole 20 mg on Demand (Maintenance Phase)	Antacid Treatment (Maintenance Phase)
Number of Participants Analyzed	0	0	0	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
Esomeprazole 20 mg Once Daily (Initial Phase)	
Esomeprazole 40 mg Once Daily (Initial Phase)	
Esomeprazole 20 mg Once Daily (Maintenance Phase)	

	Description
Esomeprazole 20 mg on Demand (Maintenance Phase)	
Antacid Treatment (Maintenance Phase)	antacid treatment as needed (maintenance phase) (Xolaam® maximum six tablets per day)

Serious Adverse Events

	Esomeprazole 20 mg Once Daily (Initial Phase)	Esomeprazole 40 mg Once Daily (Initial Phase)	Esomeprazole 20 mg Once Daily (Maintenance Phase)	Esomeprazole 20 mg on Demand (Maintenance Phase)	Antacid Treatment (Maintenance Phase)
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	8/2156 (0.37%)	2/873 (0.23%)	2/886 (0.23%)	3/880 (0.34%)	4/851 (0.47%)
Cardiac disorders					
MYOCARDIAL INFARCTION [A]	1/2156 (0.05%)	0/873 (0%)	0/886 (0%)	0/880 (0%)	0/851 (0%)
Gastrointestinal disorders					
ACUTE BALTHAZAR E PANCREATITIS [A]	1/2156 (0.05%)	0/873 (0%)	0/886 (0%)	0/880 (0%)	0/851 (0%)
ADENOMATOUS POLYP [A]	0/2156 (0%)	0/873 (0%)	1/886 (0.11%)	0/880 (0%)	0/851 (0%)
EROSIVE ANTRITIS [A]	0/2156 (0%)	1/873 (0.11%)	0/886 (0%)	0/880 (0%)	0/851 (0%)
GASTRIC ULCER [A]	0/2156 (0%)	0/873 (0%)	0/886 (0%)	1/880 (0.11%)	0/851 (0%)
General disorders					
PREEXISTING LUNG CARCINOMA AGGRAVATION [A]	1/2156 (0.05%)	0/873 (0%)	0/886 (0%)	0/880 (0%)	0/851 (0%)
Infections and infestations					
DIGESTIVE VIROSIS [A]	0/2156 (0%)	0/873 (0%)	0/886 (0%)	1/880 (0.11%)	0/851 (0%)
Musculoskeletal and connective tissue disorders					
AGGRAVATION OF INTERVERTEBRAL DISC HERNIATION [A]	0/2156 (0%)	0/873 (0%)	0/886 (0%)	0/880 (0%)	1/851 (0.12%)
SPONDYLOLISTHE SIS AGGRAVATION BY L5 SPONDYLOLYSIS [A]	0/2156 (0%)	0/873 (0%)	1/886 (0.11%)	0/880 (0%)	0/851 (0%)

	Esomeprazole 20 mg Once Daily (Initial Phase)	Esomeprazole 40 mg Once Daily (Initial Phase)	Esomeprazole 20 mg Once Daily (Maintenance Phase)	Esomeprazole 20 mg on Demand (Maintenance Phase)	Antacid Treatment (Maintenance Phase)
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
ADENOCARCINOM A OF GASTRIC ANTRUM [A]	0/2156 (0%)	0/873 (0%)	0/886 (0%)	0/880 (0%)	1/851 (0.12%)
BRONCHIAL CANCER [A]	1/2156 (0.05%)	0/873 (0%)	0/886 (0%)	0/880 (0%)	0/851 (0%)
CARCINOMA OF OESOPHAGUS [A]	1/2156 (0.05%)	0/873 (0%)	0/886 (0%)	0/880 (0%)	0/851 (0%)
Pregnancy, puerperium and perinatal conditions					
Abortion spontaneous [A]	1/2156 (0.05%)	0/873 (0%)	0/886 (0%)	0/880 (0%)	0/851 (0%)
Psychiatric disorders					
ANXIO-DEPRESSI VE STATE [A]	1/2156 (0.05%)	0/873 (0%)	0/886 (0%)	0/880 (0%)	0/851 (0%)
DEPRESSION [A]	0/2156 (0%)	0/873 (0%)	0/886 (0%)	1/880 (0.11%)	0/851 (0%)
DEPRESSIVE DISEASE [A]	1/2156 (0.05%)	0/873 (0%)	0/886 (0%)	0/880 (0%)	0/851 (0%)
Renal and urinary disorders					
RENAL COLIC [A]	0/2156 (0%)	0/873 (0%)	0/886 (0%)	0/880 (0%)	1/851 (0.12%)
Reproductive system and breast disorders					
METRORRHAGIA [A]	0/2156 (0%)	0/873 (0%)	0/886 (0%)	0/880 (0%)	1/851 (0.12%)
Respiratory, thoracic and mediastinal disorders					
PNEUMOPATHY [A]	0/2156 (0%)	1/873 (0.11%)	0/886 (0%)	0/880 (0%)	0/851 (0%)

A Term from vocabulary, MedDRA 10.0

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 0%

	Esomeprazole 20 mg Once Daily (Initial Phase)	Esomeprazole 40 mg Once Daily (Initial Phase)	Esomeprazole 20 mg Once Daily (Maintenance Phase)	Esomeprazole 20 mg on Demand (Maintenance Phase)	Antacid Treatment (Maintenance Phase)
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	32/2156 (1.48%)	16/873 (1.83%)	5/886 (0.56%)	2/880 (0.23%)	13/851 (1.53%)
Ear and labyrinth disorders					
Vertigo [A]	3/2156 (0.14%)	1/873 (0.11%)	1/886 (0.11%)	0/880 (0%)	0/851 (0%)
Gastrointestinal disorders					
Abdominal pain [A]	4/2156 (0.19%)	0/873 (0%)	0/886 (0%)	0/880 (0%)	0/851 (0%)
Abdominal pain upper [A]	0/2156 (0%)	1/873 (0.11%)	0/886 (0%)	0/880 (0%)	2/851 (0.24%)
Constipation [A]	2/2156 (0.09%)	1/873 (0.11%)	0/886 (0%)	0/880 (0%)	0/851 (0%)
Diarrhea [A]	3/2156 (0.14%)	0/873 (0%)	0/886 (0%)	0/880 (0%)	1/851 (0.12%)
Dry mouth [A]	1/2156 (0.05%)	0/873 (0%)	1/886 (0.11%)	0/880 (0%)	0/851 (0%)
Dysphagia [A]	1/2156 (0.05%)	0/873 (0%)	0/886 (0%)	0/880 (0%)	0/851 (0%)
Epigastric discomfort [A]	1/2156 (0.05%)	0/873 (0%)	0/886 (0%)	0/880 (0%)	0/851 (0%)
Flatulence [A]	0/2156 (0%)	1/873 (0.11%)	0/886 (0%)	0/880 (0%)	0/851 (0%)
Gastric ulcer [A]	0/2156 (0%)	0/873 (0%)	0/886 (0%)	1/880 (0.11%)	0/851 (0%)
Gastritis [A]	1/2156 (0.05%)	1/873 (0.11%)	0/886 (0%)	0/880 (0%)	0/851 (0%)
Gastroesophageal reflux disease [A]	0/2156 (0%)	0/873 (0%)	0/886 (0%)	0/880 (0%)	1/851 (0.12%)
Gastrointestinal disorder [A]	0/2156 (0%)	0/873 (0%)	0/886 (0%)	0/880 (0%)	2/851 (0.24%)
Nausea [A]	4/2156 (0.19%)	1/873 (0.11%)	0/886 (0%)	0/880 (0%)	1/851 (0.12%)
Oesophagitis [A]	1/2156 (0.05%)	0/873 (0%)	0/886 (0%)	0/880 (0%)	0/851 (0%)
General disorders					
Asthenia [A]	0/2156 (0%)	2/873 (0.23%)	0/886 (0%)	0/880 (0%)	0/851 (0%)

	Esomeprazole 20 mg Once Daily (Initial Phase)	Esomeprazole 40 mg Once Daily (Initial Phase)	Esomeprazole 20 mg Once Daily (Maintenance Phase)	Esomeprazole 20 mg on Demand (Maintenance Phase)	Antacid Treatment (Maintenance Phase)
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Chest pain [A]	0/2156 (0%)	1/873 (0.11%)	0/886 (0%)	0/880 (0%)	0/851 (0%)
Somnolence [A]	1/2156 (0.05%)	0/873 (0%)	0/886 (0%)	0/880 (0%)	0/851 (0%)
Metabolism and nutrition disorders					
Weight decreased [A]	1/2156 (0.05%)	0/873 (0%)	0/886 (0%)	0/880 (0%)	0/851 (0%)
Musculoskeletal and connective tissue disorders					
Intervertebral disc protrusion [A]	0/2156 (0%)	0/873 (0%)	0/886 (0%)	0/880 (0%)	1/851 (0.12%)
Myalgia [A]	1/2156 (0.05%)	0/873 (0%)	0/886 (0%)	0/880 (0%)	0/851 (0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
Gastric cancer [A]	0/2156 (0%)	0/873 (0%)	0/886 (0%)	0/880 (0%)	1/851 (0.12%)
Nervous system disorders					
Headache [A]	5/2156 (0.23%)	2/873 (0.23%)	1/886 (0.11%)	0/880 (0%)	0/851 (0%)
Psychiatric disorders					
Nervousness [A]	0/2156 (0%)	0/873 (0%)	1/886 (0.11%)	0/880 (0%)	0/851 (0%)
Respiratory, thoracic and mediastinal disorders					
Cough [A]	0/2156 (0%)	0/873 (0%)	0/886 (0%)	0/880 (0%)	1/851 (0.12%)
Lung disorder [A]	0/2156 (0%)	1/873 (0.11%)	0/886 (0%)	0/880 (0%)	0/851 (0%)
Pharyngeal stenosis [A]	0/2156 (0%)	1/873 (0.11%)	0/886 (0%)	0/880 (0%)	0/851 (0%)
Skin and subcutaneous tissue disorders					
Rash [A]	1/2156 (0.05%)	0/873 (0%)	0/886 (0%)	0/880 (0%)	0/851 (0%)
Urticaria [A]	0/2156 (0%)	1/873 (0.11%)	0/886 (0%)	0/880 (0%)	0/851 (0%)
Vascular disorders					
Dyspepsia [B]	2/2156 (0.09%)	2/873 (0.23%)	1/886 (0.11%)	1/880 (0.11%)	3/851 (0.35%)

A Term from vocabulary, MedDRA (10.0)
B Term from vocabulary, MedDRA 10.0

Limitations and Caveats

Planned number of patients not reached: statistical analysis plan revised,comparisons between treatment arms performed globally (No stratified analysis).

Safety pop=3032-3 incorrect enrolments (withdrawals at V2) with no information on ttmt received

More Information

Certain Agreements:

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

There is NOT 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.

Results Point of Contact:

Name/Official Title: Gerard Lynch
Organization: AstraZeneca
Phone:
Email: ClinicalTrialTransparency@astrazeneca.com