ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 07/12/2012

ClinicalTrials.gov ID: NCT00441727

Study Identification

Unique Protocol ID:	D961FC00003
Brief Title:	Study of Esomeprazole 20 mg or 40 mg vs Placebo Effectiveness on the Occurrence of Peptic Ulcers in Subjects on Low Dose Acetylsalicylic Acid (LDA) (Oberon)
Official Title:	A Randomized, Double-blind, Parallel-group, Multicentre, Phase III Study to Assess the Effect of Esomeprazole 20 or 40 mg od Versus Placebo on the Occurrence of Peptic Ulcers During 26 Weeks in Subjects on Continuous Low Dose Acetylsalicylic Acid (ASA)
Secondary IDs:	EudraCT No. 2006-005073-22

Study Status

Record Verification:	July 2012
Overall Status:	Completed
Study Start:	February 2007
Primary Completion:	August 2008 [Actual]
Study Completion:	August 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?:	Yes
IND/IDE Information:	Grantor: CDER IND/IDE Number: 53733 Serial Number: 377 Has Expanded Access? No
Review Board:	Approval Status: Board Name: Board Affiliation: Phone: Email:
Data Monitoring?:	
Plan to Share Data?:	
Oversight Authorities:	United States: Food and Drug Administration Argentina: Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica Australia: Department of Health and Ageing Therapeutic Goods Administration Bulgaria: Bulgarian Drug Agency Canada: Health Canada Czech Republic: State Institute for Drug Control Finland: Finnish Medicines Agency Germany: Federal Institute for Drugs and Medical Devices Hungary: National Institute of Pharmacy Mexico: Federal Commission for Protection Against Health Risks Norway: Norwegian Medicines Agency Poland: Office for Registration of Medicinal Products, Medical Devices and Biocidal Products Portugal: National Pharmacy and Medicines Institute Romania: National Medicines Agency Russia: Pharmacological Committee, Ministry of Health Slovakia: State Institute for Drug Control South Africa: Medicines Control Council Philippines: Bureau of Food and Drugs South Korea: Korea Food and Drug Administration (KFDA) Thailand: Food and Drug Administration

Study Description

Brief Summary: The purpose of this study is to compare the effect of esomeprazole 20 or 40 mg once daily versus placebo on the occurrence of peptic ulcers during 26 weeks in subjects on continuous low-dose acetylsalicylic acid.

Detailed Description:

Conditions

Conditions: Gastric Ulcer
Duodenal Ulcer

Keywords: Peptic ulcer
low-dose ASA

Study Design

Study Type: Interventional

Primary Purpose: Prevention

Study Phase: Phase 3

Intervention Model: Parallel Assignment

Number of Arms: 3

Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)

Allocation: Randomized

Endpoint Classification: Efficacy Study

Enrollment: 2426 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Esomeprazole 40 mg Esomeprazole 40 mg	Drug: Esomeprazole 40 mg Esomeprazole 40 mg once daily
Experimental: Esomeprazole 20 mg Esomeprazole 20 mg	Drug: Esomeprazole 20 mg Esomeprazole 20 mg once daily
Placebo Comparator: Placebo Placebo	Drug: Placebo Placebo once daily

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years

Maximum Age:

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- Daily intake of low-dose Aspirin (ASA) - The subject must fulfill at least one of the following (a-e):
- Aged ≥65 years.
- Aged ≥18 years and with a documented history of uncomplicated peptic ulcer(s).
- Aged ≥60 years and naïve to low-dose ASA (ie, treatment started within 1 month prior to randomization).
- Aged ≥60 years and with stable coronary artery disease.
- Aged ≥60 years and with complaints of upper gastrointestinal (GI) symptoms that, as judged by the investigator, requires an Esophagogastroduodenoscopy (EGD) and with the finding of ≥5 gastric and/or duodenal erosions at the baseline endoscopy.

Exclusion Criteria:

- Peptic ulcer(s) at baseline esophagogastroduodenoscopy (EGD).
- Reflux esophagitis Los Angeles (LA) classification grade C or D at baseline
- History of peptic ulcer complications such as clinically significant bleeding and/or perforation.

Contacts/Locations

Study Officials: Tore Lind, MD, PhD
Study Director
AstraZeneca

James Scheiman, MD
Study Principal Investigator
University of Michigan

Locations: Argentina
Research Site
Buenos Aires, Buenos Aires- Argentina, Argentina

Research Site

Capital Federal, Buenos Aires, Argentina

Research Site
Loma Hermosa, Buenos Aires, Argentina

Research Site
Lomas de Zamora, Buenos Aires, Argentina

Research Site
Mendoza, Argentina

Research Site
Rosario, Santa Fe, Argentina

Research Site
Rosario, Argentina

Australia, South Australia
Research Site
Adelaide, South Australia, Australia

Australia, Victoria
Research Site
Ballarat, Victoria, Australia

Research Site
Box Hill, Victoria, Australia

Australia, Queensland
Research Site
Caboolture, Queensland, Australia

Research Site
Carina Heights, Queensland, Australia

Australia, Victoria
Research Site
Geelong, Victoria, Australia

Australia
Research Site
NSW, Australia

Bulgaria
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Chirpan, Bulgaria

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Pleven, Bulgaria

Research Site
Rousse, Bulgaria

Research Site
Sofia, Bulgaria

Research Site
Varna, Bulgaria

Canada, Newfoundland and Labrador
Research Site
Bay Roberts, Newfoundland and Labrador, Canada

Canada, Ontario
Research Site
Brampton, Ontario, Canada

Canada, Alberta
Research Site
Calgary, Alberta, Canada

Canada, Ontario
Research Site
Cambridge, Ontario, Canada

Canada, Newfoundland and Labrador
Research Site
Carbonear, Newfoundland and Labrador, Canada

Canada, Alberta
Research Site
Edmonton, Alberta, Canada

Canada, Ontario
Research Site
Hamilton, Ontario, Canada

Canada
Research Site
Laval, Canada

Research Site
Longueuil, Canada

Canada, Newfoundland and Labrador
Research Site
Mount Pearl, Newfoundland and Labrador, Canada

Canada, Ontario
Research Site
Niagara Falls, Ontario, Canada

Research Site
North York, Ontario, Canada

Canada, Quebec
Research Site
Pointe-claire, Quebec, Canada

Canada
Research Site
Quebec, Canada

Canada, Newfoundland and Labrador
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St. John`s, Newfoundland and Labrador, Canada

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St. John's, Newfoundland and Labrador, Canada

Canada, Ontario
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Tillsonburg, Ontario, Canada

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Toronto, Ontario, Canada

Czech Republic
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Beroun, Czech Republic

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Brno, Czech Republic

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Liberec, Czech Republic

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Litomerice, Czech Republic

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Ostrava - Trebovice, Czech Republic

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Poobram, Czech Republic

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Podborany, Czech Republic

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Praha 1, Czech Republic

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Praha 4 - Sporilov, Czech Republic

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Praha 6, Czech Republic

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Praha 9, Czech Republic

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Tabor, Czech Republic

Finland
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Mikkeli, Finland

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Indonesia
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Semarang, Indonesia

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Surabaya, Indonesia

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Yogyakarta, Indonesia

Mexico
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D.F, Mexico

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Guadalajara, Jalisco, Mexico

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Mexico, D.f., Mexico

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Mexico City, Mexico

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Zapopan, Jalisco, Mexico

Norway
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Olesund, Norway

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Asker, Norway

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Bergen, Norway

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Seongnam-si, Kyeonggi-do, Korea, Republic of

Research Site
Seoul, Korea, Republic of

Romania
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Brasov, Brasov, Romania

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Bucharest, Romania

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Iasi, Iasi, Romania

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Satu-mare, Romania

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Tg. Mures, Romania

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Moscow, Russian Federation

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Saint- Petersburg, Russian Federation

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Martin, Slovakia

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Nitra, Slovakia

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Nove Mesto Nad Vahom, Slovakia

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Piestany, Slovakia

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Povazska Bystrica, Slovakia

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Trnava, Slovakia

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Cape Town, South Africa

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Durban, South Africa

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Thailand
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Bangkok, Thailand

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Chiang Mai, Thailand

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Albuquerque, New Mexico, United States

United States, California
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Anaheim, California, United States

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Anderson, South Carolina, United States

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Cincinnati, Ohio, United States

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Cranston, Rhode Island, United States

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Dayton, Ohio, United States

United States, New Jersey
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Egg Harbor Township, New Jersey, United States

United States, North Carolina
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Fayetteville, North Carolina, United States

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Fulton, Illinois, United States

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Great Neck, New York, United States

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Wichita, Kansas, United States

United States, North Carolina
Research Site
Winston-salem, North Carolina, United States

United States, Florida
Research Site
Zephyrhills, Florida, United States

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	The first subject was randomized 22 February 2007 and last subject completed 28 August 2008. Cardiologists, primary care physicians and gastroenterologists were the primary target investigators.

Reporting Groups

	Description
Esomeprazole 40	Esomeprazole 40 mg every day for 26 weeks in subjects on continuous low-dose ASA (acetylsalicyclic acid) (75-325 mg)
Esomeproazole 20	Esomeprazole 20 mg every day for 26 weeks in subjects on continuous low dose ASA (75-325 mg)
Placebo	Placebo every day for 26 weeks in subjects on continuous low-dose ASA (75-325 mg)

Overall Study

	Esomeprazole 40	Esomeproazole 20	Placebo
Started	817 [1]	804 [1]	805 [1]
Completed	711 [1]	686 [1]	637 [1]
Not Completed	106	118	168
Protocol Violation	19	28	32
Adverse Event	26	33	28
Lack of Efficacy	7	8	48
Withdrawal by Subject	40	34	47
Lost to Follow-up	5	6	5
Safety Reasons	3	1	3
Various reason specified	6	8	5

[1] ITT/randomised

Baseline Characteristics

Reporting Groups

	Description
Esomeprazole 40	Esomeprazole 40 mg every day for 26 weeks in subjects on continuous low-dose ASA (acetylsalicyclic acid) (75-325 mg)
Esomeproazole 20	Esomeprazole 20 mg every day for 26 weeks in subjects on continuous low dose ASA (75-325 mg)
Placebo	Placebo every day for 26 weeks in subjects on continuous low-dose ASA (75-325 mg)

Baseline Measures

	Esomeprazole 40	Esomeproazole 20	Placebo	Total
Number of Participants	817	804	805	2426
Age, Categorical [units: Participants]				
<=18 years	0	0	0	0
Between 18 and 65 years	240	246	260	746

	Esomeprazole 40	Esomeproazole 20	Placebo	Total
>=65 years	577	558	545	1680
Gender, Male/Female [units: Participants]				
Female	380	375	402	1157
Male	437	429	403	1269

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Percentage of Participants Who Experienced the Occurence of Peptic Ulcer(s).
Measure Description	The occurrence of ulcer (mucosal break measuring >= 3 mm over its largest diameter with a sharply demarcated margin) was determined by endoscopy performed at baseline, 8 weeks and 26 weeks or upon withdrawal.
Time Frame	During 26 weeks
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
Esomeprazole 40	Esomeprazole 40 mg every day for 26 weeks in subjects on continuous low-dose ASA (acetylsalicyclic acid) (75-325 mg)
Esomeproazole 20	Esomeprazole 20 mg every day for 26 weeks in subjects on continuous low dose ASA (75-325 mg)
Placebo	Placebo every day for 26 weeks in subjects on continuous low-dose ASA (75-325 mg)

Measured Values

	Esomeprazole 40	Esomeproazole 20	Placebo
Number of Participants Analyzed	817	804	805
Percentage of Participants Who Experienced the Occurence of Peptic Ulcer(s). [units: percentage of participants]	1.35	1	6.58

2. Secondary Outcome Measure:

Measure Title	Percentage of Participants Who Experienced the Occurence of Gastric Ulcer.
Measure Description	The occurrence of gastric ulcer (mucosal break measuring >= 3 mm over its largest diameter with a sharply demarcated margin) was determined by endoscopy performed at baseline, 8 weeks and 26 weeks or upon withdrawal.
Time Frame	During 26 weeks
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
Esomeprazole 40	Esomeprazole 40 mg every day for 26 weeks in subjects on continuous low-dose ASA (acetylsalicyclic acid) (75-325 mg)
Esomeproazole 20	Esomeprazole 20 mg every day for 26 weeks in subjects on continuous low dose ASA (75-325 mg)
Placebo	Placebo every day for 26 weeks in subjects on continuous low-dose ASA (75-325 mg)

Measured Values

	Esomeprazole 40	Esomeproazole 20	Placebo
Number of Participants Analyzed	817	804	805
Percentage of Participants Who Experienced the Occurence of Gastric Ulcer. [units: percentage of participants]	1.1	0.75	4.1

3. Secondary Outcome Measure:

Measure Title	Percentage of Participants Who Experienced the Occurrence of Duodenal Ulcer.
Measure Description	The occurrence of duodenal ulcer (mucosal break measuring >= 3 mm over its largest diameter with a sharply demarcated margin) was determined by endoscopy performed at baseline, 8 weeks and 26 weeks or upon withdrawal.
Time Frame	During 26 weeks
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
Esomeprazole 40	Esomeprazole 40 mg every day for 26 weeks in subjects on continuous low-dose ASA (acetylsalicyclic acid) (75-325 mg)
Esomeproazole 20	Esomeprazole 20 mg every day for 26 weeks in subjects on continuous low dose ASA (75-325 mg)
Placebo	Placebo every day for 26 weeks in subjects on continuous low-dose ASA (75-325 mg)

Measured Values

	Esomeprazole 40	Esomeproazole 20	Placebo
Number of Participants Analyzed	817	804	805
Percentage of Participants Who Experienced the Occurrence of Duodenal Ulcer. [units: percentage of participants]	0.24	0.25	2.73

4. Secondary Outcome Measure:

Measure Title	Number of Participants Reporting 0 in the Dichotomized RDQ (Reflux and Disease Questionnaire) Score (0 Versus >0) for the Dyspepsia Dimension During the 26-week Visit or the Week Prior to the Last Visit.
Measure Description	RDQ contains 12 items on a 6-point Likert scale. Six items concern the frequence ('Did not have' to 'Daily') and six items concern the severity ('Did not have' to 'Severe'). The dyspepsia dimension contains the items 'Burning feeling in the center of the upper stomach' and 'Pain in the center of the upper stomach'. Best score possible 0, worst score possible - daily occurrence.
Time Frame	RDQ was assessed at baseline, 8 weeks, 16 week, 26 weeks or upon withdrawal.
Safety Issue?	No

Analysis Population Description

Patients randomized who took at least one dose of study drug and completed RDQ questionnaire at baseline and at week 26 or the week prior to last visit were analyzed.

Reporting Groups

	Description
Esomeprazole 40 mg	Esomeprazole 40 mg every day for 26 weeks in subjects on continuous low-dose ASA (acetylsalicyclic acid) (75-325 mg)
Esomeprazole 20 mg	Esomeprazole 20 mg every day for 26 weeks in subjects on continuous low-dose ASA (acetylsalicyclic acid) (75-325 mg)

	Description
Placbo	Placebo every day for 26 weeks in subjects on continuous low-dose ASA (acetylsalicyclic acid) (75-325 mg)

Measured Values

	Esomeprazole 40 mg	Esomeprazole 20 mg	Placbo
Number of Participants Analyzed	782	758	763
Number of Participants Reporting 0 in the Dichotomized RDQ (Reflux and Disease Questionnaire) Score (0 Versus >0) for the Dyspepsia Dimension During the 26-week Visit or the Week Prior to the Last Visit. [units: participants]	591	577	504

5. Secondary Outcome Measure:

Measure Title	Number of Participants Reporting 0 in the Dichotomized RDQ (Reflux and Disease Questionnaire) Score (0 Versus >0) for the Gastroesophageal Reflux Disease Dimension During the 26-week Visit or the Week Prior to the Last Visit.
Measure Description	RDQ contains 12 items on a 6-point Likert scale. Six items concern the frequency ('Did not have' to 'Daily') and six items concern the severity ('Did not have' to 'Severe'). Gastroesophageal reflux disease (GERD) items: 'Acid taste in the mouth', 'Unpleasant movement of materials upward from the stomach', 'Burning feeling behind the breastbone' and 'Pain behind the breastbone'. Best score possible 0, worst score possible - daily occurrence.
Time Frame	RDQ was assessed at baseline, 8 weeks, 16 week, 26 weeks or upon withdrawal.
Safety Issue?	No

Analysis Population Description

Patients randomized who took at least one dose of study drug and completed RDQ questionnaire at baseline and at week 26 or the week prior to last visit were analyzed.

Reporting Groups

	Description
Esomeprazole 40 mg	Esomeprazole 40 mg every day for 26 weeks in subjects on continuous low-dose ASA (acetylsalicyclic acid) (75-325 mg)
Esomeproazole 20 mg	Esomeprazole 20 mg every day for 26 weeks in subjects on continuous low dose ASA (acetylsalicyclic acid) (75-325 mg)
Placebo	Placebo every day for 26 weeks in subjects on continuous low-dose ASA (acetylsalicyclic acid) (75-325 mg)

Measured Values

	Esomeprazole 40 mg	Esomeproazole 20 mg	Placebo
Number of Participants Analyzed	782	758	763
Number of Participants Reporting 0 in the Dichotomized RDQ (Reflux and Disease Questionnaire) Score (0 Versus >0) for the Gastroesophageal Reflux Disease Dimension During the 26-week Visit or the Week Prior to the Last Visit. [units: participants]	554	537	451

6. Secondary Outcome Measure:

Measure Title	Number of Participants With Gastric and/or Duodenal Erosions.
Measure Description	
Time Frame	The number of erosions was determined by endoscopy performed at baseline, 8 weeks and 26 weeks or upon withdrawal.
Safety Issue?	No

Analysis Population Description

Patients randomized who had endoscopy performed at baseline, 8 weeks and 26 weeks or upon withdrawal.

Reporting Groups

	Description
Esomeprazole 40	Esomeprazole 40 mg every day for 26 weeks in subjects on continuous low-dose ASA (acetylsalicyclic acid) (75-325 mg)
Esomeproazole 20	Esomeprazole 20 mg every day for 26 weeks in subjects on continuous low dose ASA (75-325 mg)
Placebo	Placebo every day for 26 weeks in subjects on continuous low-dose ASA (75-325 mg)

Measured Values

	Esomeprazole 40	Esomeproazole 20	Placebo
Number of Participants Analyzed	772	753	748
Number of Participants With Gastric and/or Duodenal Erosions. [units: participants]	214	213	380

Reported Adverse Events

Time Frame	[Not specified]
Additional Description	Nine (9) randomized subjects were not evaluable for safety analysis because they were never exposed to investigational product. Three (3) additional subjects were excluded from safety. They were exposed to investigational product, but did not have any post-dose data.

Reporting Groups

	Description
Esomeprazole 40	Esomeprazole 40 mg every day for 26 weeks in subjects on continuous low-dose ASA (acetylsalicyclic acid) (75-325 mg)
Esomeproazole 20	Esomeprazole 20 mg every day for 26 weeks in subjects on continuous low dose ASA (75-325 mg)
Placebo	Placebo every day for 26 weeks in subjects on continuous low-dose ASA (75-325 mg)

Serious Adverse Events

	Esomeprazole 40	Esomeproazole 20	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	46/	40/	35/
Cardiac disorders			
Acute Coronary Syndrome [A] †	0/814 (0%)	1/799 (0.13%)	0/801 (0%)
Angina Pectoris [A] †	2/814 (0.25%)	0/799 (0%)	1/801 (0.12%)
Angina Unstable [A] †	2/814 (0.25%)	0/799 (0%)	0/801 (0%)
Atrial Fibrillation [A] †	0/814 (0%)	1/799 (0.13%)	1/801 (0.12%)
Cardiac Arrest [A] †	0/814 (0%)	2/799 (0.25%)	1/801 (0.12%)
Cardiac Failure [A] †	0/814 (0%)	1/799 (0.13%)	1/801 (0.12%)
Cardiac Failure Congestive [A] †	1/814 (0.12%)	0/799 (0%)	0/801 (0%)
Coronary Artery Disease [A] †	2/814 (0.25%)	1/799 (0.13%)	1/801 (0.12%)

	Esomeprazole 40	Esomeproazole 20	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Coronary Artery Stenosis [A] †	0/814 (0%)	0/799 (0%)	1/801 (0.12%)
Myocardial Infarction [A] †	1/814 (0.12%)	1/799 (0.13%)	0/801 (0%)
Myocardial Ischaemia [A] †	1/814 (0.12%)	0/799 (0%)	0/801 (0%)
Ear and labyrinth disorders			
Vertigo [A] †	0/814 (0%)	1/799 (0.13%)	0/801 (0%)
Endocrine disorders			
Acromegaly [A] †	0/814 (0%)	0/799 (0%)	1/801 (0.12%)
Gastrointestinal disorders			
Abdominal Pain [A] †	1/814 (0.12%)	0/799 (0%)	0/801 (0%)
Abdominal Pain Upper [A] †	1/814 (0.12%)	0/799 (0%)	0/801 (0%)
Colitis [A] †	0/814 (0%)	1/799 (0.13%)	0/801 (0%)
Diarrhoea [A] †	0/814 (0%)	1/799 (0.13%)	0/801 (0%)
Diverticulum [A] †	0/814 (0%)	0/799 (0%)	1/801 (0.12%)
Duodenal Perforation [A] †	0/814 (0%)	1/799 (0.13%)	0/801 (0%)
Dyspepsia [A] †	1/814 (0.12%)	0/799 (0%)	0/801 (0%)
Gastric Ulcer [A] †	0/814 (0%)	0/799 (0%)	1/801 (0.12%)
Gastritis [A] †	1/814 (0.12%)	0/799 (0%)	0/801 (0%)
Inguinal Hernia [A] †	2/814 (0.25%)	0/799 (0%)	1/801 (0.12%)
Intestinal Ischaemia [A] †	1/814 (0.12%)	0/799 (0%)	0/801 (0%)
Intestinal Obstruction [A] †	0/814 (0%)	1/799 (0.13%)	0/801 (0%)
Irritable Bowel Syndrome [A] †	1/814 (0.12%)	1/799 (0.13%)	0/801 (0%)
Pancreatitis [A] †	0/814 (0%)	1/799 (0.13%)	0/801 (0%)

	Esomeprazole 40	Esomeproazole 20	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Pancreatitis Acute [A] †	2/814 (0.25%)	1/799 (0.13%)	0/801 (0%)
Subileus [A] †	1/814 (0.12%)	0/799 (0%)	0/801 (0%)
Vomiting [A] †	1/814 (0.12%)	1/799 (0.13%)	0/801 (0%)
General disorders			
Chest Pain [A] †	0/814 (0%)	1/799 (0.13%)	0/801 (0%)
Death [A] †	0/814 (0%)	1/799 (0.13%)	0/801 (0%)
Non-Cardiac Chest Pain [A] †	1/814 (0.12%)	0/799 (0%)	1/801 (0.12%)
Sudden Death [A] †	1/814 (0.12%)	0/799 (0%)	0/801 (0%)
Hepatobiliary disorders			
Cholecystitis [A] †	0/814 (0%)	0/799 (0%)	1/801 (0.12%)
Cholecystitis Acute [A] †	1/814 (0.12%)	1/799 (0.13%)	0/801 (0%)
Cholelithiasis [A] †	0/814 (0%)	1/799 (0.13%)	0/801 (0%)
Hepatitis Toxic [A] †	0/814 (0%)	1/799 (0.13%)	0/801 (0%)
Infections and infestations			
Bronchitis [A] †	0/814 (0%)	1/799 (0.13%)	0/801 (0%)
Diverticulitis [A] †	1/814 (0.12%)	0/799 (0%)	0/801 (0%)
Erysipelas [A] †	1/814 (0.12%)	0/799 (0%)	0/801 (0%)
Lobar Pneumonia [A] †	0/814 (0%)	1/799 (0.13%)	0/801 (0%)
Meningitis [A] †	0/814 (0%)	0/799 (0%)	1/801 (0.12%)
Pyelonephritis [A] †	1/814 (0.12%)	0/799 (0%)	0/801 (0%)
Pyelonephritis Acute [A] †	1/814 (0.12%)	0/799 (0%)	0/801 (0%)
Sepsis [A] †	1/814 (0.12%)	0/799 (0%)	0/801 (0%)

	Esomeprazole 40	Esomeproazole 20	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Urinary Tract Infection [A] †	0/814 (0%)	0/799 (0%)	1/801 (0.12%)
Injury, poisoning and procedural complications			
Arthropod Bite [A] †	1/814 (0.12%)	0/799 (0%)	0/801 (0%)
Dislocation Of Joint Prosthesis [A] †	0/814 (0%)	0/799 (0%)	1/801 (0.12%)
Femur Fracture [A] †	0/814 (0%)	0/799 (0%)	1/801 (0.12%)
Hand Fracture [A] †	0/814 (0%)	0/799 (0%)	1/801 (0.12%)
Humerus Fracture [A] †	0/814 (0%)	0/799 (0%)	1/801 (0.12%)
Joint Dislocation [A] †	1/814 (0.12%)	0/799 (0%)	0/801 (0%)
Upper Limb Fracture [A] †	0/814 (0%)	0/799 (0%)	1/801 (0.12%)
Vascular Graft Occlusion [A] †	1/814 (0.12%)	0/799 (0%)	0/801 (0%)
Wrist Fracture [A] †	0/814 (0%)	0/799 (0%)	1/801 (0.12%)
Metabolism and nutrition disorders			
Diabetes Mellitus [A] †	0/814 (0%)	1/799 (0.13%)	0/801 (0%)
Gout [A] †	1/814 (0.12%)	0/799 (0%)	0/801 (0%)
Hypokalaemia [A] †	0/814 (0%)	1/799 (0.13%)	0/801 (0%)
Hyponatraemia [A] †	0/814 (0%)	1/799 (0.13%)	0/801 (0%)
Musculoskeletal and connective tissue disorders			
Arthritis [A] †	0/814 (0%)	1/799 (0.13%)	1/801 (0.12%)
Back Pain [A] †	1/814 (0.12%)	0/799 (0%)	0/801 (0%)
Flank Pain [A] †	0/814 (0%)	0/799 (0%)	1/801 (0.12%)
Osteoarthritis [A] †	1/814 (0.12%)	0/799 (0%)	0/801 (0%)
Pain In Extremity [A] †	0/814 (0%)	0/799 (0%)	1/801 (0.12%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

	Esomeprazole 40	Esomeproazole 20	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Adenocarcinoma [A] †	1/814 (0.12%)	0/799 (0%)	1/801 (0.12%)
Adenocarcinoma Pancreas [A] †	0/814 (0%)	0/799 (0%)	1/801 (0.12%)
Bile Duct Cancer [A] †	0/814 (0%)	0/799 (0%)	1/801 (0.12%)
Gastric Cancer [A] †	1/814 (0.12%)	0/799 (0%)	1/801 (0.12%)
Gastrointestinal Tract Adenoma [A] †	0/814 (0%)	0/799 (0%)	1/801 (0.12%)
Lentigo Maligna Stage Unspecified [A] †	0/814 (0%)	1/799 (0.13%)	0/801 (0%)
Lung Neoplasm Malignant [A] †	1/814 (0.12%)	1/799 (0.13%)	0/801 (0%)
Oesophageal Adenocarcinoma [A] †	0/814 (0%)	1/799 (0.13%)	1/801 (0.12%)
Oesophageal Carcinoma [A] †	1/814 (0.12%)	0/799 (0%)	0/801 (0%)
Prostate Cancer [A] †	1/814 (0.12%)	0/799 (0%)	0/801 (0%)
Rectal Cancer [A] †	0/814 (0%)	0/799 (0%)	1/801 (0.12%)
Renal Cell Carcinoma [A] †	0/814 (0%)	1/799 (0.13%)	0/801 (0%)
Signet-Ring Cell Carcinoma [A] †	1/814 (0.12%)	0/799 (0%)	0/801 (0%)
Thyroid Cancer [A] †	0/814 (0%)	1/799 (0.13%)	0/801 (0%)
Transitional Cell Carcinoma [A] †	0/814 (0%)	0/799 (0%)	1/801 (0.12%)
Nervous system disorders			
Carotid Arteriosclerosis [A] †	0/814 (0%)	0/799 (0%)	1/801 (0.12%)
Cerebral Circulatory Failure [A] †	0/814 (0%)	1/799 (0.13%)	0/801 (0%)
Cerebral Infarction [A] †	0/814 (0%)	1/799 (0.13%)	0/801 (0%)
Cerebrovascular Accident [A] †	1/814 (0.12%)	2/799 (0.25%)	0/801 (0%)
Dizziness [A] †	0/814 (0%)	0/799 (0%)	1/801 (0.12%)
Syncope [A] †	1/814 (0.12%)	1/799 (0.13%)	0/801 (0%)

	Esomeprazole 40	Esomeproazole 20	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Transient Ischaemic Attack [A] †	0/814 (0%)	2/799 (0.25%)	0/801 (0%)
Renal and urinary disorders			
Benign Prostatic Hyperplasia [A] †	1/814 (0.12%)	0/799 (0%)	0/801 (0%)
Nephrolithiasis [A] †	1/814 (0.12%)	0/799 (0%)	0/801 (0%)
Renal Failure Acute [A] †	1/814 (0.12%)	0/799 (0%)	0/801 (0%)
Respiratory, thoracic and mediastinal disorders			
Asthma [A] †	1/814 (0.12%)	0/799 (0%)	0/801 (0%)
Epistaxis [A] †	0/814 (0%)	1/799 (0.13%)	0/801 (0%)
Pneumothorax [A] †	0/814 (0%)	1/799 (0.13%)	0/801 (0%)
Pulmonary Sarcoidosis [A] †	0/814 (0%)	1/799 (0.13%)	0/801 (0%)
Skin and subcutaneous tissue disorders			
Skin Ulcer [A] †	0/814 (0%)	1/799 (0.13%)	0/801 (0%)
Vascular disorders			
Deep Vein Thrombosis [A] †	1/814 (0.12%)	0/799 (0%)	0/801 (0%)
Hypertensive Crisis [A] †	0/814 (0%)	0/799 (0%)	1/801 (0.12%)
Thromboangiitis Obliterans [A] †	0/814 (0%)	0/799 (0%)	1/801 (0.12%)
Varicose Vein [A] †	1/814 (0.12%)	0/799 (0%)	0/801 (0%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 11.0

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 2%

	Esomeprazole 40	Esomeproazole 20	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	32/	42/	31/
Gastrointestinal disorders			
Diarrhoea [A] †	21/814 (2.58%)	26/799 (3.25%)	18/801 (2.25%)
Respiratory, thoracic and mediastinal disorders			
Bronchitis [A] †	11/814 (1.35%)	16/799 (2%)	13/801 (1.62%)

† Indicates events were collected by systematic assessment.

A Term from vocabulary, MedDRA 11.0

Limitations and Caveats

Not enough patients had peptic ulcer, gastric ulcer, or duodenal ulcer to report the intended primary endpoint of time to peptic ulcer and two secondary endpoints, time to gastric ulcer and time to duodenal ulcer. Percentage used instead.

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.

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