ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 05/18/2011

ClinicalTrials.gov ID: NCT00251979

Study Identification

Unique Protocol ID:	D961DC00001
Brief Title:	A Study to Prevent Rebleeding After Initial Successful Primary Endoscopic Haemostasis of a Bleeding Peptic Ulcer
Official Title:	A Randomised, Double-blind, Parallel-group, Placebo Controlled Study of Esomeprazole i.v. (Bolus Infusion of 80 mg Followed by a Continuous Infusion of 8 mg Per Hour) Administered for 72 Hours to Assess Prevention of Rebleeding in Subjects That Have Undergone Successful Primary Endoscopic Haemostasis of a Bleeding Peptic Ulcer - the PUB Study.
Secondary IDs:	

Study Status

Record Verification:	May 2011
Overall Status:	Completed
Study Start:	October 2005
Primary Completion:	December 2007 [Actual]
Study Completion:	December 2007 [Actual]

Sponsor/Collaborators

Sponsor:	AstraZeneca
Responsible Party:	
Collaborators:	

Oversight

FDA Regulated?:	

IND/IDE Protocol?:	No
Review Board:	Approval Status: Approval Number: 2005/799-31 Board Name: Regionala etikprövningsnämnden i Stockholm Board Affiliation: Medical Products Agency Phone: +46 8524 800 00 Email: kansli@stockholm.epn.se
Data Monitoring?:	
Plan to Share Data?:	
Oversight Authorities:	Sweden: Medical Products Agency

Study Description

Brief Summary:	This study is being carried out to see if constant 3 days infusion of Nexium is effective in preventing rebleeding after an endoscopic treatment.
Detailed Description:	

Conditions

Conditions:	Gastrointestinal Hemorrhage
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Prevention
Study Phase:	Phase 3
Intervention Model:	Parallel Assignment
Number of Arms:	
Masking:	Double Blind
Allocation:	Randomized
Endpoint Classification:	Efficacy Study
Enrollment:	1312 [Actual]

Arms and Interventions

Intervention Details:
Drug: Esomeprazole

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years

Maximum Age:

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- Signs of a bleeding in the stomach
- One endoscopically confirmed bleeding ulcer in the stomach or duodenum

Exclusion Criteria:

- Malignancy or other advanced disease.
- Major cardiovascular event.
- Severe hepatic disease

Contacts/Locations

Study Officials: AstraZeneca Nexium Medical Sciences Director
Study Director
AstraZeneca

Joseph Sung, MD
Study Principal Investigator
The Chinese University of Hong Kong

Locations: Spain
Research Site
Madrid, Spain

Research Site

Sabadell, Spain

Research Site
Barcelona, Spain

France
Research Site
Lille, France

Research Site
Rouen, France

Research Site
Amiens, France

Research Site
Nice Cedex 3, France

Research Site
Clermont-Ferrand CEDEX 1, France

Research Site
Paris Cedex 13, France

Research Site
Bordeaux, France

Research Site
Paris Cedex 12, France

Greece
Research Site
Athens, Greece

Research Site
Thessaloniki, Greece

Norway
Research Site
Kristiansand, Norway

Finland
Research Site
Helsinki, Finland

Romania

Research Site
Iasi, Romania

Research Site
Craiova, Romania

Research Site
Bucharest, Romania

Research Site
Tg. Mures, Romania

Hong Kong
Research Site
Hong Kong, Hong Kong

Netherlands
Research Site
Arnhem, Netherlands

Research Site
Zwolle, Netherlands

Research Site
Hengelo, Netherlands

Research Site
Dordrecht, Netherlands

Research Site
Rotterdam, Netherlands

Research Site
Nieuwegein, Netherlands

South Africa
Research Site
Pietermaritzburg, South Africa

Russian Federation
Research Site
Moscow, Russian Federation

Austria
Research Site
Braunau/Inn, Austria

Research Site
Feldbach, Austria

Research Site
Graz, Austria

Research Site
Krems, Austria

Research Site
Wels, Austria

Research Site
Wien, Austria

Denmark
Research Site
Aalborg, Denmark

Research Site
Glostrup, Denmark

Research Site
Holstebro, Denmark

Research Site
Kobenhavn, Denmark

Research Site
Odense, Denmark

Research Site
Randers, Denmark

Research Site
Slagelse, Denmark

Research Site
Amager, Denmark

Norway
Research Site
Lorenskog, Norway

Research Site
Oslo, Norway

South Africa
Research Site
Cape Town, South Africa

Research Site
Bloemfontein, South Africa

Spain
Research Site
Santiago, Spain

Sweden
Research Site
Karlstad, Sweden

Research Site
Kristianstad, Sweden

Research Site
Linköping, Sweden

Research Site
Norrkoping, Sweden

Research Site
Ostersund, Sweden

Research Site
Skövde, Sweden

Research Site
Stockholm, Sweden

Research Site
Sundsvall, Sweden

Research Site
Trollhättan, Sweden

Turkey
Research Site
Izmir, Turkey

Research Site
Izmit, Turkey

Germany
Research Site
Dresden, Germany

Research Site
Leipzig, Germany

Research Site
Magdeburg, Germany

Research Site
Berlin, Germany

Research Site
Bochum, Germany

Research Site
Celle, Germany

Research Site
Karlsruhe, Germany

Research Site
Ludwigshafen, Germany

Research Site
Weimar, Germany

United Kingdom
Research Site
Birmingham, United Kingdom

Research Site
Derby, United Kingdom

Research Site
Leeds, United Kingdom

Norway
Research Site
Alesund, Norway

Research Site
Drammen, Norway

Research Site

Tonsberg, Norway

Romania
Research Site
Timisoara, Romania

Sweden
Research Site
Goteborg, Sweden

Finland
Research Site
Kuopio, Finland

Turkey
Research Site
Ankara, Turkey

Research Site
Bursa, Turkey

Russian Federation
Research Site
Saint Petersburg, Russian Federation

Finland
Research Site
Helsinki, Finland

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

Reporting Groups

	Description
Esomeprazole	Esomeprazole iv for 72 h followed by esomeprazole oral 40 mg od for 27 days
Placebo	Placebo iv for 72 h followed by esomeprazole oral 40 mg od for 27 days

Overall Study

	Esomeprazole	Placebo
Started	375 [1]	389 [1]
Completed	337	349
Not Completed	38	40
Protocol Violation	3	5
Adverse Event	11	17
Withdrawal by Subject	13	7
Lost to Follow-up	8	6
Death	3	5

[1] ITT population

Baseline Characteristics

Reporting Groups

	Description
Esomeprazole	Esomeprazole iv for 72 h followed by esomeprazole oral 40 mg od for 27 days
Placebo	Placebo iv for 72 h followed by esomeprazole oral 40 mg od for 27 days

Baseline Measures

	Esomeprazole	Placebo	Total
Number of Participants	375	389	764

	Esomeprazole	Placebo	Total
Age, Categorical [units: Participants]			
<=18 years	0	0	0
Between 18 and 65 years	182	210	392
>=65 years	193	179	372
Gender, Male/Female [units: Participants]			
Female	121	121	242
Male	254	268	522

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Clinically Significant Rebleeding Within 72 Hours of Continous Infusion of Esomeprazole or Placebo
Measure Description	
Time Frame	Within 72 hours
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Esomeprazole	Esomeprazole iv for 72 h followed by esomeprazole oral 40 mg od for 27 days
Placebo	Placebo iv for 72 h followed by esomeprazole oral 40 mg od for 27 days

Measured Values

	Esomeprazole	Placebo
Number of Participants Analyzed	375	389
Clinically Significant Rebleeding Within 72 Hours of Continous Infusion of Esomeprazole or Placebo [units: Participants]	22	40

2. Secondary Outcome Measure:

Measure Title	Clinically Significant Rebleeding Within 7 Days
Measure Description	
Time Frame	Within 7 days
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Esomeprazole	Esomeprazole iv for 72 h followed by esomeprazole oral 40 mg od for 27 days
Placebo	Placebo iv for 72 h followed by esomeprazole oral 40 mg od for 27 days

Measured Values

	Esomeprazole	Placebo
Number of Participants Analyzed	375	389
Clinically Significant Rebleeding Within 7 Days [units: Participants]	27	50

3. Secondary Outcome Measure:

Measure Title	Clinically Significant Rebleeding Within 30 Days
Measure Description	
Time Frame	Within 30 days
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Esomeprazole	Esomeprazole iv for 72 h followed by esomeprazole oral 40 mg od for 27 days
Placebo	Placebo iv for 72 h followed by esomeprazole oral 40 mg od for 27 days

Measured Values

	Esomeprazole	Placebo
Number of Participants Analyzed	375	389
Clinically Significant Rebleeding Within 30 Days [units: Participants]	29	53

4. Secondary Outcome Measure:

Measure Title	Death Within 72 Hours
Measure Description	
Time Frame	Within 72 hours
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
Esomeprazole	Esomeprazole iv for 72 h followed by esomeprazole oral 40 mg od for 27 days
Placebo	Placebo iv for 72 h followed by esomeprazole oral 40 mg od for 27 days

Measured Values

	Esomeprazole	Placebo
Number of Participants Analyzed	375	389
Death Within 72 Hours [units: Participants]	1	0

5. Secondary Outcome Measure:

Measure Title	Death Within 30 Days
Measure Description	
Time Frame	Within 30 days
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Esomeprazole	Esomeprazole iv for 72 h followed by esomeprazole oral 40 mg od for 27 days
Placebo	Placebo iv for 72 h followed by esomeprazole oral 40 mg od for 27 days

Measured Values

	Esomeprazole	Placebo
Number of Participants Analyzed	375	389
Death Within 30 Days [units: Participants]	3	8

6. Secondary Outcome Measure:

Measure Title	Death Related to Rebleeding Within 30 Days as Judged by the EpC
Measure Description	
Time Frame	Within 30 days
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Esomeprazole	Esomeprazole iv for 72 h followed by esomeprazole oral 40 mg od for 27 days
Placebo	Placebo iv for 72 h followed by esomeprazole oral 40 mg od for 27 days

Measured Values

	Esomeprazole	Placebo
Number of Participants Analyzed	375	389
Death Related to Rebleeding Within 30 Days as Judged by the EpC [units: Participants]	2	3

7. Secondary Outcome Measure:

Measure Title	Requirement for Surgery Within 72 Hours
Measure Description	
Time Frame	Within 72 hours
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Esomeprazole	Esomeprazole iv for 72 h followed by esomeprazole oral 40 mg od for 27 days
Placebo	Placebo iv for 72 h followed by esomeprazole oral 40 mg od for 27 days

Measured Values

	Esomeprazole	Placebo
Number of Participants Analyzed	375	389
Requirement for Surgery Within 72 Hours [units: Participants]	5	9

8. Secondary Outcome Measure:

Measure Title	Requirement for Surgery Within 30 Days
Measure Description	

Time Frame	Within 30 days
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Esomeprazole	Esomeprazole iv for 72 h followed by esomeprazole oral 40 mg od for 27 days
Placebo	Placebo iv for 72 h followed by esomeprazole oral 40 mg od for 27 days

Measured Values

	Esomeprazole	Placebo
Number of Participants Analyzed	375	389
Requirement for Surgery Within 30 Days [units: Participants]	10	21

9. Secondary Outcome Measure:

Measure Title	Requirement for Endoscopic Re-treatment Within 72 Hours
Measure Description	
Time Frame	Within 72 hours
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Esomeprazole	Esomeprazole iv for 72 h followed by esomeprazole oral 40 mg od for 27 days
Placebo	Placebo iv for 72 h followed by esomeprazole oral 40 mg od for 27 days

Measured Values

	Esomeprazole	Placebo
Number of Participants Analyzed	375	389
Requirement for Endoscopic Re-treatment Within 72 Hours [units: Participants]	16	32

10. Secondary Outcome Measure:

Measure Title	Requirement for Endoscopic Re-treatment Within 30 Days
Measure Description	
Time Frame	Within 30 days
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Esomeprazole	Esomeprazole iv for 72 h followed by esomeprazole oral 40 mg od for 27 days
Placebo	Placebo iv for 72 h followed by esomeprazole oral 40 mg od for 27 days

Measured Values

	Esomeprazole	Placebo
Number of Participants Analyzed	375	389
Requirement for Endoscopic Re-treatment Within 30 Days [units: Participants]	24	45

11. Secondary Outcome Measure:

Measure Title	Number of Blood Units Transfused Within 72 Hours
Measure Description	

Time Frame	Within 72 hours
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Esomeprazole	Esomeprazole iv for 72 h followed by esomeprazole oral 40 mg od for 27 days
Placebo	Placebo iv for 72 h followed by esomeprazole oral 40 mg od for 27 days

Measured Values

	Esomeprazole	Placebo
Number of Participants Analyzed	375	389
Number of Blood Units Transfused Within 72 Hours [units: blood units]	492	738

12. Secondary Outcome Measure:

Measure Title	Number of Blood Units Transfused Within 30 Days
Measure Description	
Time Frame	within 30 days
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Esomeprazole	Esomeprazole iv for 72 h followed by esomeprazole oral 40 mg od for 27 days
Placebo	Placebo iv for 72 h followed by esomeprazole oral 40 mg od for 27 days

Measured Values

	Esomeprazole	Placebo
Number of Participants Analyzed	375	389
Number of Blood Units Transfused Within 30 Days [units: blood units]	589	935

13. Secondary Outcome Measure:

Measure Title	Number of Days Hospitalized Due to Rebleeding During the 30-day Treatment Period
Measure Description	
Time Frame	Within 30 days
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
Esomeprazole	Esomeprazole iv for 72 h followed by esomeprazole oral 40 mg od for 27 days
Placebo	Placebo iv for 72 h followed by esomeprazole oral 40 mg od for 27 days

Measured Values

	Esomeprazole	Placebo
Number of Participants Analyzed	375	389
Number of Days Hospitalized Due to Rebleeding During the 30-day Treatment Period [units: days]	284	500

Reported Adverse Events

Time Frame	[Not specified]

Additional Description	[Not specified]

Reporting Groups

	Description
Esomeprazole	Esomeprazole iv for 72 h followed by esomeprazole oral 40 mg od for 27 days
Placebo	Placebo iv for 72 h followed by esomeprazole oral 40 mg od for 27 days

Serious Adverse Events

	Esomeprazole	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)
Total	61/	68/
Cardiac disorders		
ACUTE MYOCARDIAL INFARCTION [A] †	1/375 (0.27%)	2/389 (0.51%)
ANGINA PECTORIS [A] †	1/375 (0.27%)	0/389 (0%)
ANGINA UNSTABLE [A] †	1/375 (0.27%)	0/389 (0%)
ATRIAL FIBRILLATION [A] †	0/375 (0%)	3/389 (0.77%)
BRADYCARDIA [A] †	1/375 (0.27%)	0/389 (0%)
CARDIAC FAILURE [A] †	1/375 (0.27%)	0/389 (0%)
MYOCARDIAL INFARCTION [A] †	4/375 (1.07%)	5/389 (1.29%)
Congenital, familial and genetic disorders		
GASTROINTESTINAL ANGIODYSPLASIA HAEMORRHAGIC [A] †	0/375 (0%)	1/389 (0.26%)
Eye disorders		
UVEITIS [A] †	1/375 (0.27%)	0/0
Gastrointestinal disorders		
COLONIC POLYP [A] †	0/375 (0%)	1/389 (0.26%)
CONSTIPATION [A] †	0/375 (0%)	1/389 (0.26%)
DUODENAL PERFORATION [A] †	0/375 (0%)	1/389 (0.26%)

	Esomeprazole	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)
DUODENAL ULCER HAEMORRHAGE [A] †	16/375 (4.27%)	21/389 (5.4%)
DUODENAL ULCER PERFORATION [A] †	0/375 (0%)	1/389 (0.26%)
GASTRIC ULCER HAEMORRHAGE [A] †	7/375 (1.87%)	13/389 (3.34%)
GASTRIC ULCER PERFORATION [A] †	0/375 (0%)	1/389 (0.26%)
GASTROINTESTINAL HAEMORRHAGE [A] †	1/375 (0.27%)	1/389 (0.26%)
MELAENA [A] †	2/375 (0.53%)	0/389 (0%)
PANCREATITIS ACUTE [A] †	0/375 (0%)	1/389 (0.26%)
PEPTIC ULCER PERFORATION [A] †	0/375 (0%)	1/389 (0.26%)
PERITONITIS [A] †	0/375 (0%)	1/389 (0.26%)
RECTAL HAEMORRHAGE [A] †	1/375 (0.27%)	0/389 (0%)
Hepatobiliary disorders		
CHOLECYSTITIS [A] †	1/375 (0.27%)	0/389 (0%)
Infections and infestations		
ERYSIPELAS [A] †	0/375 (0%)	1/389 (0.26%)
FATIGUE [A] †	1/375 (0.27%)	0/389 (0%)
GASTROENTERITIS [A] †	1/375 (0.27%)	0/389 (0%)
LOWER RESPIRATORY TRACT INFECTION [A] †	1/375 (0.27%)	0/389 (0%)
LUNG INFECTION [A] †	1/375 (0.27%)	0/389 (0%)
PNEUMONIA [A] †	1/375 (0.27%)	0/389 (0%)
RESPIRATORY TRACT INFECTION [A] †	1/375 (0.27%)	0/389 (0%)
URINARY TRACT INFECTION [A] †	0/375 (0%)	1/389 (0.26%)

	Esomeprazole	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)
Injury, poisoning and procedural complications		
DISLOCATION OF JOINT PROSTHESIS [A] †	1/375 (0.27%)	0/389 (0%)
HIP FRACTURE [A] †	1/375 (0.27%)	0/389 (0%)
PNEUMOTHORAX TRAUMATIC [A] †	0/375 (0%)	1/389 (0.26%)
SUBDURAL HAEMORRHAGE [A] †	1/375 (0.27%)	0/389 (0%)
Metabolism and nutrition disorders		
DIABETES MELLITUS [A] †	1/375 (0.27%)	0/389 (0%)
DIABETES MELLITUS INADEQUATE CONTROL [A] †	1/375 (0.27%)	0/389 (0%)
DISCOMFORT [A] †	1/375 (0.27%)	0/389 (0%)
GOUT [A] †	2/375 (0.53%)	1/389 (0.26%)
HYPONATRAEMIA [A] †	0/375 (0%)	1/389 (0.26%)
Musculoskeletal and connective tissue disorders		
GOUTY ARTHRITIS [A] †	0/375 (0%)	3/389 (0.77%)
HAEMOGLOBIN DECREASED [A] †	0/375 (0%)	1/389 (0.26%)
OSTEOLYSIS [A] †	1/375 (0.27%)	0/389 (0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
ADENOCARCINOMA PANCREAS [A] †	0/375 (0%)	1/389 (0.26%)
BENIGN GASTRIC NEOPLASM [A] †	0/375 (0%)	1/389 (0.26%)
GASTRIC CANCER [A] †	3/375 (0.8%)	1/389 (0.26%)
GASTROINTESTINAL STROMAL TUMOUR [A] †	1/375 (0.27%)	0/389 (0%)
RECTAL CANCER [A] †	0/375 (0%)	1/389 (0.26%)

	Esomeprazole	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)
TESTICULAR CANCER METASTATIC [A] †	0/375 (0%)	1/389 (0.26%)
Nervous system disorders		
DIZZINESS [A] †	0/375 (0%)	1/389 (0.26%)
PERIPHERAL NERVE LESION [A] †	1/375 (0.27%)	0/389 (0%)
PRESYNCOPE [A] †	1/375 (0.27%)	0/389 (0%)
SYNCOPE [A] †	1/375 (0.27%)	0/389 (0%)
TRANSIENT ISCHAEMIC ATTACK [A] †	0/375 (0%)	1/389 (0.26%)
Psychiatric disorders		
ACUTE PSYCHOSIS [A] †	1/375 (0.27%)	0/389 (0%)
Renal and urinary disorders		
RENAL FAILURE [A] †	0/375 (0%)	1/389 (0.26%)
Respiratory, thoracic and mediastinal disorders		
CHRONIC OBSTRUCTIVE PULMONARY DISEASE [A] †	1/375 (0.27%)	0/389 (0%)
LUNG DISORDER [A] †	0/375 (0%)	1/389 (0.26%)
LUNG INFILTRATION [A] †	0/375 (0%)	1/389 (0.26%)
PLEURAL EFFUSION [A] †	1/375 (0.27%)	0/389 (0%)
PULMONARY EMBOLISM [A] †	0/375 (0%)	2/389 (0.51%)
PULMONARY OEDEMA [A] †	0/375 (0%)	1/389 (0.26%)
PYREXIA [A] †	1/375 (0.27%)	0/389 (0%)
RESPIRATORY FAILURE [A] †	1/375 (0.27%)	1/389 (0.26%)
Skin and subcutaneous tissue disorders		
URTICARIA [A] *	1/375 (0.27%)	0/0

	Esomeprazole	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)
Vascular disorders		
PHLEBITIS [A] †	1/375 (0.27%)	0/389 (0%)
SHOCK [A] †	1/375 (0.27%)	0/389 (0%)
THROMBOSIS [A] †	1/375 (0.27%)	0/389 (0%)
VENOUS THROMBOSIS LIMB [A] †	1/375 (0.27%)	0/0

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

Other Adverse Events

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

	Esomeprazole	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)
Total	87/375 (23.2%)	129/389 (33.16%)
Blood and lymphatic system disorders		
ANAEMIA [A] †	0/375 (0%)	6/389 (1.54%)
Gastrointestinal disorders		
ABDOMINAL PAIN [A] †	0/375 (0%)	13/389 (3.34%)
ABDOMINAL PAIN UPPER [A] †	6/375 (1.6%)	10/389 (2.57%)
CONSTIPATION [A] †	10/375 (2.67%)	15/389 (3.86%)
DIARRHOEA [A] †	7/375 (1.87%)	0/389 (0%)
NAUSEA [A] †	11/375 (2.93%)	10/389 (2.57%)
Infections and infestations		
CYSTITIS [A] †	0/375 (0%)	6/389 (1.54%)
URINARY TRACT INFECTION [A] †	7/375 (1.87%)	8/389 (2.06%)
Metabolism and nutrition disorders		

	Esomeprazole	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)
HYPOKALAEMIA [A] †	0/375 (0%)	7/389 (1.8%)
Nervous system disorders		
DIZZINESS [A] †	6/375 (1.6%)	5/389 (1.29%)
HEADACHE [A] †	8/375 (2.13%)	11/389 (2.83%)
Psychiatric disorders		
INSOMNIA [A] †	0/375 (0%)	9/389 (2.31%)
Respiratory, thoracic and mediastinal disorders		
DYSPNOEA [A] †	0/375 (0%)	8/389 (2.06%)
Skin and subcutaneous tissue disorders		
PYREXIA [A] †	17/375 (4.53%)	14/389 (3.6%)
Vascular disorders		
HYPERTENSION [A] †	6/375 (1.6%)	7/389 (1.8%)
PHLEBITIS [A] †	9/375 (2.4%)	0/389 (0%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 10.0

Limitations and Caveats

None

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.

AstraZeneca shall have a period of 30 days from receipt of the proposed final manuscript for any publication or other disclosure to review it and may within such time require that submission for publication or disclosure of the manuscript be delayed.

Results Point of Contact:

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Organization: AstraZeneca

Phone:

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