ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 02/14/2013

ClinicalTrials.gov ID: NCT00394472

Study Identification

Unique Protocol ID:	D9120C00011
Brief Title:	Symptom Improvements in Gastroesophageal Reflux Disease (GERD) Patients
Official Title:	A Randomized, Double-blind, Placebo Controlled, Phase IIA Study to Assess the Effect on Gastroesophageal Reflux Disease (GERD) Symptoms, Pharmacokinetics, Safety and Tolerability of 4 Weeks Treatment With AZD3355 65 mg Bid as add-on Treatment to a Proton Pump Inhibitor (PPI) in Patients With an Incomplete Response to PPI.
Secondary IDs:	EUDRACT No 2006-003541-16

Study Status

Record Verification:	February 2013
Overall Status:	Completed
Study Start:	November 2006
Primary Completion:	June 2007 [Actual]
Study Completion:	June 2007 [Actual]

Sponsor/Collaborators

Sponsor:	AstraZeneca
Responsible Party:	Sponsor
Collaborators:	

Oversight

FDA Regulated?:	

IND/IDE Protocol?:	No
Review Board:	Approval Status: Approved Approval Number: 06/8614 Board Name: Ethics Committee of University of Bergen (Regional komite for medisinsk forskningsetik) Board Affiliation: University of Bergen Phone: +47 55 97 84 97 Email: rek-vest@uib.no
Data Monitoring?:	
Plan to Share Data?:	
Oversight Authorities:	Norway: Norwegian Medicines Agency Australia: Department of Health and Ageing Therapeutic Goods Administration Belgium: Federal Agency for Medicines and Health Products, FAMHP France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis) Germany: Federal Institute for Drugs and Medical Devices Hungary: National Institute of Pharmacy Romania: National Medicines Agency Netherlands: The Central Committee on Research Involving Human Subjects (CCMO)

Study Description

Brief Summary:	The purpose of this study is to estimate the effect of AZD3355 as an add-on treatment to a Proton Pump Inhibitor (PPI) on Gastroesophageal reflux disease (GERD) symptoms in patients with an incomplete response to PPI treatment.
Detailed Description:	

Conditions

Conditions:	Gastroesophageal Reflux Disease (GERD)
Keywords:	Heartburn Patient reported symptoms Proton pump inhibitor

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 2
Intervention Model:	Parallel Assignment

Number of Arms:	
Masking:	Double Blind
Allocation:	Randomized
Endpoint Classification:	Safety/Efficacy Study
Enrollment:	244 [Actual]

Arms and Interventions

Intervention Details:
Drug: AZD3355

Other Names:

- Lesogaberan

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age:	17 Years
Maximum Age:	70 Years
Gender:	Both
Accepts Healthy Volunteers?:	No
Criteria:	Inclusion Criteria:

- Provision of written informed consent
- At least 6 months history of Gastroesophageal reflux disease (GERD) symptoms
- Continuous treatment with Proton Pump Inhibitor (PPI)
- Ability to read and write

Exclusion Criteria:

- Prior surgery of the upper gastrointestinal (GI) tract
- History of clinically significant diseases other than GERD
- Need for concomitant medication with drugs that may influence gastrointestinal symptoms

Contacts/Locations

Study Officials: Göran Hasselgren, MD
Study Director
AstraZeneca

Guy Boeckxstaens, MD
Study Principal Investigator
Academisch Medisch Centrum Universiteit van Amsterdam

Locations: Australia
Research Site
Adelaide, Australia

Belgium
Research Site
Brussels, Belgium

Research Site
Eupen, Belgium

Research Site
Wilrijk, Belgium

France
Research Site
Ales, France

Research Site
Angers, France

Research Site
Bordeaux, France

Research Site
Lyon, France

Research Site
Nantes, France

Germany
Research Site
Koblenz, Germany

Research Site

Koln, Germany

Research Site
Ludwigshafen, Germany

Research Site
Munchen, Germany

Research Site
Oelde, Germany

Research Site
Potsdam, Germany

Research Site
Wangen, Germany

Research Site
Wiesbaden, Germany

Hungary
Research Site
Budapest, Hungary

Research Site
Gyor, Hungary

Research Site
Pecs, Hungary

Research Site
Szombathely, Hungary

Research Site
VAC, Hungary

Netherlands
Research Site
Amsterdam, Netherlands

Norway
Research Site
Alesund, Norway

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Bergen, Norway

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Oslo, Norway

Research Site
Stavanger, Norway

Research Site
Tromso, Norway

Romania
Research Site
Targu Mures, Romania

Research Site
Bucharest, Romania

Research Site
Satu-mare, Romania

Research Site
Brasov, Romania

Norway
Research Site
Trondheim, Norway

Research Site
RUD, Norway

Research Site
Levanger, Norway

Hungary
Research Site
Szeged, Hungary

Research Site
Siofok, Hungary

Research Site
Nagykanizsa, Hungary

References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Reporting Groups

	Description
AZD3355	AZD3355 capsules 65 mg bid
Placebo	Placebo capsules bid

Overall Study

	AZD3355	Placebo
Started	122	122
Completed	113	111
Not Completed	9	11
Protocol Violation	1	3
incorrect enrolment	4	2
Adverse Event	4	2
Withdrawal by Subject	0	2
Physician Decision	0	1
Lost to Follow-up	0	1

Baseline Characteristics

Reporting Groups

	Description
AZD3355	AZD3355 capsules 65 mg bid
Placebo	Placebo capsules bid

Baseline Measures

	AZD3355	Placebo	Total
Number of Participants	122	122	244
Age, Continuous [units: years] Mean (Standard Deviation)	51.1 (11.9)	48.7 (12.6)	49.9 (12.3)
Gender, Male/Female [units: Participants]			
Female	51	31	82
Male	71	91	162

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Number of Participants With at Most One Day With Not More Than Mild Intensity of the Symptoms 'a Burning Feeling Behind the Breastbone' and 'Unpleasant Movement of Material Upwards From the Stomach' During the Last Seven Days of Treatment
Measure Description	Symptom intensity rated by participants twice daily on a six-graded Likert scale (Did not have; Very mild; Mild; Moderate; Moderately severe; Severe) using an electronic Reflux Disease Questionnaire (RDQ) diary
Time Frame	Twice daily during the last seven days on treatment
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
AZD3355	AZD3355 capsules 65 mg bid
Placebo	Placebo capsules bid

Measured Values

	AZD3355	Placebo
Number of Participants Analyzed	114	118

	AZD3355	Placebo
Number of Participants With at Most One Day With Not More Than Mild Intensity of the Symptoms 'a Burning Feeling Behind the Breastbone' and 'Unpleasant Movement of Material Upwards From the Stomach' During the Last Seven Days of Treatment [units: Participants]	17	8

2. Secondary Outcome Measure:

Measure Title	Plasma Concentration (µmol/L) of AZD3355 Analysed From Blood Sample Taken in the Interval One to Two Hours After the First Intake of AZD3355 65 mg Capsule
Measure Description	
Time Frame	An interval of one to two hours after the first intake of AZD3355 65 mg capsule
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
AZD3355	AZD3355 capsules 65 mg bid
Placebo	Placebo capsules bid

Measured Values

	AZD3355	Placebo
Number of Participants Analyzed	122	0
Plasma Concentration (µmol/L) of AZD3355 Analysed From Blood Sample Taken in the Interval One to Two Hours After the First Intake of AZD3355 65 mg Capsule [units: µmol/L] Mean (Standard Deviation)	0.96 (0.74)	

Reported Adverse Events

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

Reporting Groups

	Description
AZD3355	AZD3355 capsules 65 mg bid
Placebo	Placebo capsules bid

Serious Adverse Events

	AZD3355	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)
Total	2/	0/
Infections and infestations		
Appendicitis [A] *	1/122 (0.82%)	0/122 (0%)
Vascular disorders		
Hypertension [A] *	1/122 (0.82%)	0/122 (0%)

* 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: 5%

	AZD3355	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)
Total	28/	19/
Gastrointestinal disorders		
DIARRHOEA [A] *	13/122 (10.66%)	4/122 (3.28%)
NAUSEA [A] *	9/122 (7.38%)	4/122 (3.28%)
General disorders		

	AZD3355	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)
FATIGUE [A] *	7/122 (5.74%)	7/122 (5.74%)
Nervous system disorders		
PARAESTHESIA [A] *	10/122 (8.2%)	6/122 (4.92%)

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

Limitations and Caveats

[Not specified]

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.

AZ shall have 30 days from the proposed final manuscript for any disclosure to review it and may within such time require that submission for publication/ disclosure be delayed in order for AZ to file patent applications. If study site/investigator requests permission to publish data(incl oral presentations) it is to be agreed with AZ before publ.

Results Point of Contact:

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