ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 08/17/2012

ClinicalTrials.gov ID: NCT01154634

Study Identification

Unique Protocol ID:	D3830C00001
Brief Title:	Study to Investigate the Pharmacodynamic Effect of a Single Dose of AZD2516 in Healthy Male Subjects
Official Title:	A Double-blind, Randomized, Placebo-controlled, Two-centre, Phase IIa Pharmacodynamic Cross-over Study to Assess the Effect of AZD2516 on the Total Number of Reflux Episodes in Healthy Male Volunteers
Secondary IDs:	

Study Status

Record Verification:	August 2012
Overall Status:	Completed
Study Start:	May 2010
Primary Completion:	September 2010 [Actual]
Study Completion:	September 2010 [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: 19 April, 2010 Board Name: Medisch Ethische Toetsingscommissie Board Affiliation: Academisch Medisch Centrum, Amsterdam Phone: +31 (0) 20 566 9111 Email:
Data Monitoring?:	No
Plan to Share Data?:	
Oversight Authorities:	Belgium: Federal Agency for Medicinal Products and Health Products Netherlands: The Central Committee on Research Involving Human Subjects (CCMO)

Study Description

Brief Summary:	The purpose of this study is to investigate the pharmacodynamic effect of AZD2516 in healthy male subjects.
Detailed Description:	A double-blind, randomized, placebo-controlled, two-centre, phase IIa pharmacodynamic cross-over study to assess the effect of AZD2516 on the total number of reflux episodes in healthy male volunteers.

Conditions

Conditions:	Reflux
Keywords:	Pharmacodynamic effect Reflux inhibition

Study Design

Study Type:	Interventional
Primary Purpose:	Basic Science
Study Phase:	Phase 2
Intervention Model:	Crossover Assignment
Number of Arms:	4
Masking:	Double Blind (Subject, Caregiver, Investigator)
Allocation:	Randomized
Endpoint Classification:	Pharmacodynamics Study

Enrollment: 20 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: First 5 mg, then placebo, then 16 mg, then 40 mg period 1: AZD2516 5 mg, period 2: washout, period 3: placebo, period 4: washout, period 5: AZD2516 16 mg, period 6: washout, period 7: AZD2516 40 mg.	Drug: AZD2516, 5 mg Capsule, oral Drug: AZD2516, 16 mg Capsule, oral Drug: AZD2516, 40 mg Capsule, oral Drug: Placebo Capsule, oral
Experimental: First 40 mg, then 16 mg, then placebo, then 5 mg period 1: AZD2516 40 mg, period 2: washout, period 3: AZD2516 16 mg, period 4: washout, period 5: placebo, period 6: washout, period 7: AZD2516 5 mg.	Drug: AZD2516, 5 mg Capsule, oral Drug: AZD2516, 16 mg Capsule, oral Drug: AZD2516, 40 mg Capsule, oral Drug: Placebo Capsule, oral
Experimental: First 16 mg, then 5 mg, then 40 mg, then placebo period 1: AZD2516 16 mg, period 2: washout, period 3: AZD2516 5 mg, period 4: washout, period 5: AZD2516 40 mg, period 6: washout, period 7: placebo.	Drug: AZD2516, 5 mg Capsule, oral Drug: AZD2516, 16 mg Capsule, oral Drug: AZD2516, 40 mg Capsule, oral Drug: Placebo Capsule, oral
Experimental: First placebo, then 40 mg, then 5 mg, then 16 mg period 1: placebo, period 2: washout, period 3: AZD2516 40 mg, period 4: washout, period 5: AZD2516 5 mg, period 6: washout, period 7: AZD2516 16 mg	Drug: AZD2516, 5 mg Capsule, oral Drug: AZD2516, 16 mg Capsule, oral Drug: AZD2516, 40 mg Capsule, oral Drug: Placebo Capsule, oral

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age:	18 Years
Maximum Age:	45 Years
Gender:	Male
Accepts Healthy Volunteers?:	Yes
Criteria:	Inclusion Criteria:

- Provision of signed informed consent
- Healthy male subjects
- Age 18-45 years, inclusive

Exclusion Criteria:

- Clinically significant illness within the 2 weeks prior to the first dose of study drug
- History of clinically significant cardiovascular, respiratory, renal, hepatic, neurological, mental or gastrointestinal disease
- Need for concomitant medications during the study

Contacts/Locations

Study Officials: Mark Berner Hansen
Study Director
AstraZeneca R&D Molndal

Locations: Belgium
Research Site
Leuven, Belgium

Netherlands
Research Site
Amsterdam, Netherlands

References

Citations:

Links:

Study Data/Documents:

Participant Flow

Recruitment Details	In total 25 participants were enrolled into the study at 2 medical centres (14 and 11 participants), 20 of them were randomised to treatment (10 at each medical centre) and all these 20 participants completed the study.
Pre-Assignment Details	After enrolment, participant's eligibility for assignment to treatment was based on inclusion and exclusion criteria.

Reporting Groups

	Description
First 5 mg, Then Placebo, Then 16 mg, Then 40 mg	period 1: AZD2516 5 mg, period 2: washout, period 3: placebo, period 4: washout, period 5: AZD2516 16 mg, period 6: washout, period 7: AZD2516 40 mg.
First 40 mg, Then 16 mg, Then Placebo, Then 5 mg	period 1: AZD2516 40 mg, period 2: washout, period 3: AZD2516 16 mg, period 4: washout, period 5: placebo, period 6: washout, period 7: AZD2516 5 mg.
First 16 mg, Then 5 mg, Then 40 mg, Then Placebo	period 1: AZD2516 16 mg, period 2: washout, period 3: AZD2516 5 mg, period 4: washout, period 5: AZD2516 40 mg, period 6: washout, period 7: placebo.
First Placebo, Then 40 mg, Then 5 mg, Then 16 mg	period 1: placebo, period 2: washout, period 3: AZD2516 40 mg, period 4: washout, period 5: AZD2516 5 mg, period 6: washout, period 7: AZD2516 16 mg

Period 1 - First Intervention

	First 5 mg, Then Placebo, Then 16 mg, Then 40 mg	First 40 mg, Then 16 mg, Then Placebo, Then 5 mg	First 16 mg, Then 5 mg, Then 40 mg, Then Placebo	First Placebo, Then 40 mg, Then 5 mg, Then 16 mg
Started	4	7	4	5
Completed	4	7	4	5
Not Completed	0	0	0	0

Period 2 - Washout

	First 5 mg, Then Placebo, Then 16 mg, Then 40 mg	First 40 mg, Then 16 mg, Then Placebo, Then 5 mg	First 16 mg, Then 5 mg, Then 40 mg, Then Placebo	First Placebo, Then 40 mg, Then 5 mg, Then 16 mg
Started	4	7	4	5
Completed	4	7	4	5
Not Completed	0	0	0	0

Period 3- Second Intervention

	First 5 mg, Then Placebo, Then 16 mg, Then 40 mg	First 40 mg, Then 16 mg, Then Placebo, Then 5 mg	First 16 mg, Then 5 mg, Then 40 mg, Then Placebo	First Placebo, Then 40 mg, Then 5 mg, Then 16 mg
Started	4	7	4	5
Completed	4	7	4	5
Not Completed	0	0	0	0

Period 4 - Washout

	First 5 mg, Then Placebo, Then 16 mg, Then 40 mg	First 40 mg, Then 16 mg, Then Placebo, Then 5 mg	First 16 mg, Then 5 mg, Then 40 mg, Then Placebo	First Placebo, Then 40 mg, Then 5 mg, Then 16 mg
Started	4	7	4	5
Completed	4	7	4	5
Not Completed	0	0	0	0

Period 5 - Third Intervention

	First 5 mg, Then Placebo, Then 16 mg, Then 40 mg	First 40 mg, Then 16 mg, Then Placebo, Then 5 mg	First 16 mg, Then 5 mg, Then 40 mg, Then Placebo	First Placebo, Then 40 mg, Then 5 mg, Then 16 mg
Started	4	7	4	5
Completed	4	7	4	5
Not Completed	0	0	0	0

Period 6 - Washout

	First 5 mg, Then Placebo, Then 16 mg, Then 40 mg	First 40 mg, Then 16 mg, Then Placebo, Then 5 mg	First 16 mg, Then 5 mg, Then 40 mg, Then Placebo	First Placebo, Then 40 mg, Then 5 mg, Then 16 mg
Started	4	7	4	5
Completed	4	7	4	5
Not Completed	0	0	0	0

Period 7 - Fourth Intervention

	First 5 mg, Then Placebo, Then 16 mg, Then 40 mg	First 40 mg, Then 16 mg, Then Placebo, Then 5 mg	First 16 mg, Then 5 mg, Then 40 mg, Then Placebo	First Placebo, Then 40 mg, Then 5 mg, Then 16 mg
Started	4	7	4	5
Completed	4	7	4	5
Not Completed	0	0	0	0

Baseline Characteristics

Reporting Groups

	Description
AZD2516 5 mg	Loading dose: 3 * AZD2516 1 mg capsules. Maintenance doses: 1 * AZD2516 1 mg capsule, 2 * placebo capsules and 1 * AZD2516 1 mg capsule, 2 * placebo capsules.
AZD2516 16 mg	Loading dose: 2 * AZD2516 5mg capsule, 1 * placebo capsule. Maintenance dose: 3 * AZD2516 1 mg capsule and 3 * AZD2516 1 mg capsule.
AZD2516 40 mg	Loading dose: 2 * AZD2616 10 mg capsules, 1 * placebo capsule. Maintenance dose: 2 * AZD2616 5 mg capsules, 1 * placebo capsule and 2 * AZD2616 5 mg capsules, 1 * placebo capsule.
Placebo	Loading dose: 3 * placebo capsules. Maintenance dose: 3 * placebo capsules and 3 * placebo capsules.

Baseline Measures

	AZD2516 5 mg	AZD2516 16 mg	AZD2516 40 mg	Placebo	Total
Number of Participants	4	7	4	5	20
Age, Continuous Age (years) [units: years] Mean (Standard Deviation)	31 (9.6)	25 (4.5)	28.8 (5.9)	23 (4.2)	26.95 (6.3)
Gender, Male/Female [units: Participants]					
Female	0	0	0	0	0
Male	4	7	4	5	20

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Reflux Episodes 0 to 3 Hours Post Meal

Measure Description	Total number of reflux episodes 0 to 3 hours post meal
Time Frame	0 to 3 hours post meal
Safety Issue?	No

Analysis Population Description

Data from two subjects (one in arm AZD2516 5 mg, and one in arm Placebo) were excluded from efficacy analysis due to incorrect medication received.

Reporting Groups

	Description
AZD2516 5 mg	Loading dose: 3 * AZD2516 1 mg capsules. Maintenance doses: 1 * AZD2516 1 mg capsule, 2 * placebo capsules and 1 * AZD2516 1 mg capsule, 2 * placebo capsules.
AZD2516 16 mg	Loading dose: 2 * AZD2516 5mg capsule, 1 * placebo capsule. Maintenance dose: 3 * AZD2516 1 mg capsule and 3 * AZD2516 1 mg capsule.
AZD2516 40 mg	Loading dose: 2 * AZD2616 10 mg capsules, 1 * placebo capsule. Maintenance dose: 2 * AZD2616 5 mg capsules, 1 * placebo capsule and 2 * AZD2616 5 mg capsules, 1 * placebo capsule.
Placebo	Loading dose: 3 * placebo capsules. Maintenance dose: 3 * placebo capsules and 3 * placebo capsules.

Measured Values

	AZD2516 5 mg	AZD2516 16 mg	AZD2516 40 mg	Placebo
Number of Participants Analyzed	19	20	20	19
Reflux Episodes 0 to 3 Hours Post Meal [units: Episodes] Geometric Mean (Full Range)	15.1 (1 to 149)	12.5 (0 to 50)	11.0 (0 to 41)	12.7 (0 to 40)

2. Secondary Outcome Measure:

Measure Title	Transient Lower Esophagus Sphincter Relaxations (TLESRs) 0 to 3 Hours Post Meal
Measure Description	Number of TLESRs 0 to 3 hours post meal were calculated based upon the manometric analysis fpr the 3-hour post-meal period.
Time Frame	0 to 3 hours post meal
Safety Issue?	No

Analysis Population Description

Data from two subjects were excluded from efficacy analysis due to incorrect medication received Data from five visits from two subject were excluded form analysis due to deviations caused by technical problems.

Reporting Groups

	Description
AZD2516 5 mg	Loading dose: 3 * AZD2516 1 mg capsules. Maintenance doses: 1 * AZD2516 1 mg capsule, 2 * placebo capsules and 1 * AZD2516 1 mg capsule, 2 * placebo capsules.
AZD2516 16 mg	Loading dose: 2 * AZD2516 5mg capsule, 1 * placebo capsule. Maintenance dose: 3 * AZD2516 1 mg capsule and 3 * AZD2516 1 mg capsule.
AZD2516 40 mg	Loading dose: 2 * AZD2616 10 mg capsules, 1 * placebo capsule. Maintenance dose: 2 * AZD2616 5 mg capsules, 1 * placebo capsule and 2 * AZD2616 5 mg capsules, 1 * placebo capsule.
Placebo	Loading dose: 3 * placebo capsules. Maintenance dose: 3 * placebo capsules and 3 * placebo capsules.

Measured Values

	AZD2516 5 mg	AZD2516 16 mg	AZD2516 40 mg	Placebo
Number of Participants Analyzed	18	19	18	18
Transient Lower Esophagus Sphincter Relaxations (TLESRs) 0 to 3 Hours Post Meal [units: relaxations] Geometric Mean (Full Range)	16.9 (8 to 51)	16.2 (9 to 26)	10.4 (2 to 31)	16.8 (9 to 33)

3. Secondary Outcome Measure:

Measure Title	Area Under the Plasma Concentration Curve(AUC)
Measure Description	Area under the plasma concentration vs. time curve from time zero to 12-hours post dose calculated by loglinear trapezoidal method
Time Frame	0 to 12 hours post dose
Safety Issue?	No

Analysis Population Description

Data from one subject in arm AZD2516 5 mg were excluded from efficacy analysis due to incorrect medication received.

Reporting Groups

	Description
AZD2516 5 mg	Loading dose: 3 * AZD2516 1 mg capsules. Maintenance doses: 1 * AZD2516 1 mg capsule, 2 * placebo capsules and 1 * AZD2516 1 mg capsule, 2 * placebo capsules.

	Description
AZD2516 16 mg	Loading dose: 2 * AZD2516 5mg capsule, 1 * placebo capsule. Maintenance dose: 3 * AZD2516 1 mg capsule and 3 * AZD2516 1 mg capsule.
AZD2516 40 mg	Loading dose: 2 * AZD2616 10 mg capsules, 1 * placebo capsule. Maintenance dose: 2 * AZD2616 5 mg capsules, 1 * placebo capsule and 2 * AZD2616 5 mg capsules, 1 * placebo capsule.
Placebo	Loading dose: 3 * placebo capsules. Maintenance dose: 3 * placebo capsules and 3 * placebo capsules.

Measured Values

	AZD2516 5 mg	AZD2516 16 mg	AZD2516 40 mg	Placebo
Number of Participants Analyzed	19	20	20	0
Area Under the Plasma Concentration Curve(AUC) [units: nmol*h/L] Geometric Mean (95% Confidence Interval)	251.5 (188.4 to 335.7)	906.6 (732.7 to 1122)	2825 (2185 to 3653)	

4. Secondary Outcome Measure:

Measure Title	Average Plasma Concentration (C Average)
Measure Description	Average plasma concentration
Time Frame	1 to 4 hours post dose
Safety Issue?	No

Analysis Population Description

Data from one subject in arm AZD2516 5 mg were excluded from efficacy analysis due to incorrect medication received.

Reporting Groups

	Description
AZD2516 5 mg	Loading dose: 3 * AZD2516 1 mg capsules. Maintenance doses: 1 * AZD2516 1 mg capsule, 2 * placebo capsules and 1 * AZD2516 1 mg capsule, 2 * placebo capsules.
AZD2516 16 mg	Loading dose: 2 * AZD2516 5mg capsule, 1 * placebo capsule. Maintenance dose: 3 * AZD2516 1 mg capsule and 3 * AZD2516 1 mg capsule.
AZD2516 40 mg	Loading dose: 2 * AZD2616 10 mg capsules, 1 * placebo capsule. Maintenance dose: 2 * AZD2616 5 mg capsules, 1 * placebo capsule and 2 * AZD2616 5 mg capsules, 1 * placebo capsule.
Placebo	Loading dose: 3 * placebo capsules. Maintenance dose: 3 * placebo capsules and 3 * placebo capsules.

Measured Values

	AZD2516 5 mg	AZD2516 16 mg	AZD2516 40 mg	Placebo
Number of Participants Analyzed	19	20	20	0
Average Plasma Concentration (C Average) [units: nmol/L] Geometric Mean (95% Confidence Interval)	45.46 (35.04 to 58.98)	175.8 (142.4 to 217.1)	506.8 (405.0 to 634.3)	

5. Secondary Outcome Measure:

Measure Title	Maximum Plasma Concentration (Cmax)
Measure Description	Maximum plasma concentration
Time Frame	0 to 12 hours post dose
Safety Issue?	No

Analysis Population Description

Data from one subject in arm AZD2516 5 mg were excluded from efficacy analysis due to incorrect medication received.

Reporting Groups

	Description
AZD2516 5 mg	Loading dose: 3 * AZD2516 1 mg capsules. Maintenance doses: 1 * AZD2516 1 mg capsule, 2 * placebo capsules and 1 * AZD2516 1 mg capsule, 2 * placebo capsules.
AZD2516 16 mg	Loading dose: 2 * AZD2516 5mg capsule, 1 * placebo capsule. Maintenance dose: 3 * AZD2516 1 mg capsule and 3 * AZD2516 1 mg capsule.
AZD2516 40 mg	Loading dose: 2 * AZD2616 10 mg capsules, 1 * placebo capsule. Maintenance dose: 2 * AZD2616 5 mg capsules, 1 * placebo capsule and 2 * AZD2616 5 mg capsules, 1 * placebo capsule.
Placebo	Loading dose: 3 * placebo capsules. Maintenance dose: 3 * placebo capsules and 3 * placebo capsules.

Measured Values

	AZD2516 5 mg	AZD2516 16 mg	AZD2516 40 mg	Placebo
Number of Participants Analyzed	19	20	20	0
Maximum Plasma Concentration (Cmax) [units: nmol/L] Geometric Mean (95% Confidence Interval)	103.8 (76.09 to 141.5)	378.0 (315.0 to 453.5)	911.7 (767.3 to 1083)	

6. Secondary Outcome Measure:

Measure Title	Time to Maximum Plasma Concentration (Tmax)
Measure Description	Time to maximum plasma concentration (Tmax)
Time Frame	0 to 12 hours post dose
Safety Issue?	No

Analysis Population Description

Data from one subject in arm AZD2516 5 mg were excluded from efficacy analysis due to incorrect medication received.

Reporting Groups

	Description
AZD2516 5 mg	Loading dose: 3 * AZD2516 1 mg capsules. Maintenance doses: 1 * AZD2516 1 mg capsule, 2 * placebo capsules and 1 * AZD2516 1 mg capsule, 2 * placebo capsules.
AZD2516 16 mg	Loading dose: 2 * AZD2516 5mg capsule, 1 * placebo capsule. Maintenance dose: 3 * AZD2516 1 mg capsule and 3 * AZD2516 1 mg capsule.
AZD2516 40 mg	Loading dose: 2 * AZD2616 10 mg capsules, 1 * placebo capsule. Maintenance dose: 2 * AZD2616 5 mg capsules, 1 * placebo capsule and 2 * AZD2616 5 mg capsules, 1 * placebo capsule.
Placebo	Loading dose: 3 * placebo capsules. Maintenance dose: 3 * placebo capsules and 3 * placebo capsules.

Measured Values

	AZD2516 5 mg	AZD2516 16 mg	AZD2516 40 mg	Placebo
Number of Participants Analyzed	19	20	20	0
Time to Maximum Plasma Concentration (Tmax) [units: hours] Median (Full Range)	0.750 (0.500 to 4.000)	0.750 (0.500 to 1.250)	1.000 (0.500 to 4.000)	

7. Secondary Outcome Measure:

Measure Title	Terminal Half-life (T Half)
Measure Description	Terminal half-life (T half)
Time Frame	0 to 12 hours post dose
Safety Issue?	No

Analysis Population Description

Data from one subject in arm AZD2516 5 mg were excluded from efficacy analysis due to incorrect medication received.

Two samples were not analyzed for T half due to technical reasons.

Reporting Groups

	Description
AZD2516 5 mg	Loading dose: 3 * AZD2516 1 mg capsules. Maintenance doses: 1 * AZD2516 1 mg capsule, 2 * placebo capsules and 1 * AZD2516 1 mg capsule, 2 * placebo capsules.
AZD2516 16 mg	Loading dose: 2 * AZD2516 5mg capsule, 1 * placebo capsule. Maintenance dose: 3 * AZD2516 1 mg capsule and 3 * AZD2516 1 mg capsule.
AZD2516 40 mg	Loading dose: 2 * AZD2616 10 mg capsules, 1 * placebo capsule. Maintenance dose: 2 * AZD2616 5 mg capsules, 1 * placebo capsule and 2 * AZD2616 5 mg capsules, 1 * placebo capsule.
Placebo	Loading dose: 3 * placebo capsules. Maintenance dose: 3 * placebo capsules and 3 * placebo capsules.

Measured Values

	AZD2516 5 mg	AZD2516 16 mg	AZD2516 40 mg	Placebo
Number of Participants Analyzed	17	20	20	0
Terminal Half-life (T Half) [units: hours] Geometric Mean (95% Confidence Interval)	1.221 (1.042 to 1.430)	1.416 (1.222 to 1.640)	1.584 (1.414 to 1.774)	

8. Secondary Outcome Measure:

Measure Title	Clinically Relevant Change of Laboratory Variables
Measure Description	Number of participants with clinically relevant change of laboratory variables as judged by the responsible medical officer.
Time Frame	Pre-entry to follow-up
Safety Issue?	Yes

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
AZD2516 5 mg	Loading dose: 3 * AZD2516 1 mg capsules. Maintenance doses: 1 * AZD2516 1 mg capsule, 2 * placebo capsules and 1 * AZD2516 1 mg capsule, 2 * placebo capsules.
AZD2516 16 mg	Loading dose: 2 * AZD2516 5mg capsule, 1 * placebo capsule. Maintenance dose: 3 * AZD2516 1 mg capsule and 3 * AZD2516 1 mg capsule.
AZD2516 40 mg	Loading dose: 2 * AZD2616 10 mg capsules, 1 * placebo capsule. Maintenance dose: 2 * AZD2616 5 mg capsules, 1 * placebo capsule and 2 * AZD2616 5 mg capsules, 1 * placebo capsule.
Placebo	Loading dose: 3 * placebo capsules. Maintenance dose: 3 * placebo capsules and 3 * placebo capsules.

Measured Values

	AZD2516 5 mg	AZD2516 16 mg	AZD2516 40 mg	Placebo
Number of Participants Analyzed	20	20	20	20
Clinically Relevant Change of Laboratory Variables [units: Participants]	0	0	0	0

Reported Adverse Events

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

Reporting Groups

	Description
AZD2516 5 mg	Loading dose: 3 * AZD2516 1 mg capsules. Maintenance doses: 1 * AZD2516 1 mg capsule, 2 * placebo capsules and 1 * AZD2516 1 mg capsule, 2 * placebo capsules.
AZD2516 16 mg	Loading dose: 2 * AZD2516 5mg capsule, 1 * placebo capsule. Maintenance dose: 3 * AZD2516 1 mg capsule and 3 * AZD2516 1 mg capsule.
AZD2516 40 mg	Loading dose: 2 * AZD2616 10 mg capsules, 1 * placebo capsule. Maintenance dose: 2 * AZD2616 5 mg capsules, 1 * placebo capsule and 2 * AZD2616 5 mg capsules, 1 * placebo capsule.
Placebo	Loading dose: 3 * placebo capsules. Maintenance dose: 3 * placebo capsules and 3 * placebo capsules.

Serious Adverse Events

	AZD2516 5 mg	AZD2516 16 mg	AZD2516 40 mg	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	0/20 (0%)	0/20 (0%)	0/20 (0%)	0/20 (0%)

Other Adverse Events

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

	AZD2516 5 mg	AZD2516 16 mg	AZD2516 40 mg	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	4/20 (20%)	8/20 (40%)	12/20 (60%)	3/20 (15%)
Ear and labyrinth disorders				
Vertigo [A]	0/20 (0%)	0/20 (0%)	1/20 (5%)	0/20 (0%)
Eye disorders				
Diplopia [A]	0/20 (0%)	0/20 (0%)	1/20 (5%)	0/20 (0%)
Vision Blurred [A]	0/20 (0%)	0/20 (0%)	1/20 (5%)	0/20 (0%)
Gastrointestinal disorders				
Abdominal Pain [A]	0/20 (0%)	0/20 (0%)	1/20 (5%)	0/20 (0%)
Flatulence [A]	0/20 (0%)	0/20 (0%)	1/20 (5%)	2/20 (10%)
Gastrointestinal Pain [A]	0/20 (0%)	0/20 (0%)	0/20 (0%)	1/20 (5%)
Nervous system disorders				
Balance Disorder [A]	0/20 (0%)	0/20 (0%)	1/20 (5%)	0/20 (0%)
Disturbance In Attention [A]	2/20 (10%)	5/20 (25%)	4/20 (20%)	0/20 (0%)
Dizziness [A]	0/20 (0%)	1/20 (5%)	7/20 (35%)	0/20 (0%)
Headache [A]	1/20 (5%)	3/20 (15%)	2/20 (10%)	0/20 (0%)
Paraesthesia [A]	0/20 (0%)	0/20 (0%)	1/20 (5%)	0/20 (0%)
Sinus Headache [A]	1/20 (5%)	0/20 (0%)	0/20 (0%)	0/20 (0%)
Somnolence [A]	1/20 (5%)	0/20 (0%)	1/20 (5%)	0/20 (0%)

	AZD2516 5 mg	AZD2516 16 mg	AZD2516 40 mg	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Psychiatric disorders				
Daydreaming [A]	0/20 (0%)	0/20 (0%)	1/20 (5%)	0/20 (0%)
Euphoric Mood [A]	0/20 (0%)	2/20 (10%)	2/20 (10%)	0/20 (0%)
Renal and urinary disorders				
Pyuria [A]	0/20 (0%)	0/20 (0%)	0/20 (0%)	1/20 (5%)

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.

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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