ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 01/20/2014

ClinicalTrials.gov ID: NCT01173471

## Study Identification

| | |
|---|---|
| Unique Protocol ID: | D4250C00001 |
| Brief Title: | A Phase IIa Study to Assess the Tolerability, Safety, and Efficacy of AZD4017 for Raised Intra-ocular Pressure |
| Official Title: | A Double Masked, Placebo Controlled, Randomised, Parallel Group Phase IIa Study to Assess the Tolerability, Safety, and Efficacy of AZD4017 for Raised Intra-Ocular Pressure |
| Secondary IDs: | 2010-020932-20 [EudraCT Number] |

## Study Status

| | |
|---|---|
| Record Verification: | January 2014 |
| Overall Status: | Completed |
| Study Start: | December 2010 |
| Primary Completion: | November 2012 [Actual] |
| Study Completion: | November 2012 [Actual] |

## Sponsor/Collaborators

| | |
|---|---|
| Sponsor: | AstraZeneca |
| Responsible Party: | Sponsor |
| Collaborators: | |

## Oversight

| | |
|---|---|
| FDA Regulated?: | No |
| IND/IDE Protocol?: | No |

| | |
|---|---|
| Review Board: | Approval Status: Approved<br>Approval Number: 10/H0402/57<br>Board Name: Leicestershire, Northamptonshire and Rutland Research Ethics Committee 2<br>Board Affiliation: Leicestershire, Northamptonshire and Rutland Research Ethics Committee 2<br>Phone: 0115 8839 428<br>Email: Susie.Cornick-Willis@nottspct.nhs.uk |
| Data Monitoring?: | No |
| Plan to Share Data?: | |
| Oversight Authorities: | United Kingdom: Medicines and Healthcare Products Regulatory Agency<br>United Kingdom: Research Ethics Committee |

## Study Description

| | |
|---|---|
| Brief Summary: | The purpose of this study is to evaluate the efficacy of systemically administered AZD4017, compared with placebo, over a 28-day period in patients with raised intra-ocular pressure (IOP). |
| Detailed Description: | |

## Conditions

| | |
|---|---|
| Conditions: | Raised Intraocular Pressure |
| Keywords: | Raised intraocular pressure |

## Study Design

| | |
|---|---|
| Study Type: | Interventional |
| Primary Purpose: | Basic Science |
| Study Phase: | Phase 2 |
| Intervention Model: | Parallel Assignment |
| Number of Arms: | 4 |
| Masking: | Double Blind (Subject, Investigator) |
| Allocation: | Randomized |
| Endpoint Classification: | Safety/Efficacy Study |
| Enrollment: | 50 [Actual] |

## Arms and Interventions

| Arms | Assigned Interventions |
|---|---|
| Experimental: 1) AZD4017<br>Europe: 200 mg AZD4017 | Drug: AZD4017<br>tablet, oral, one tablet once daily, 28 days |
| Placebo Comparator: 2) Placebo<br>Europe: placebo | Drug: Placebo<br>matching placebo tablet, oral, one tablet once daily, 28 days |
| Experimental: 3) AZD4017<br>USA: 800 mg AZD4017 | Drug: AZD4017<br>tablet, oral 2 tablets twice daily, 28 days |
| Placebo Comparator: 4) Placebo<br>USA: placebo | Drug: Placebo<br>matching placebo tablets, oral, 2 tablets twice daily, 28 days |

## Outcome Measures

[See Results Section.]

## Eligibility

Minimum Age: 18 Years

Maximum Age: 80 Years

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- Must have a diagnosis of intra-ocular hypertension (raised IOP), or primary open-angle glaucoma (POAG), with IOP >20 mmHg and ≤36 mmHg in the study eye, and is currently prescribed a stable dose of a single anti-glaucoma medication that began at least 30 days prior to the screening visit; OR
- Must have a diagnosis of intra-ocular hypertension (raised IOP), defined as an IOP ≥22 mmHg and ≤36 mmHg in the study eye while not on anti-glaucoma medication
- Male patients must be willing to use barrier contraception with spermicide, ie, condoms, from the day of first dosing until 3 months after dosing with IP
- Placebo treatment for duration of the study must not be considered detrimental to the patient

Exclusion Criteria:

- Have uncontrolled intra-ocular hypertension (>36 mmHg)
- Have experienced a significant visual field loss or showed evidence of progressive visual field loss within the last year (as defined by >1 dB/yr average loss or vision threatening new defect)
- Have had severe eye trauma at any time

## Contacts/Locations

Study Officials: Heather Bryson, PhD
Study Director
AstraZeneca R&D

Tony Ho, MD
Study Director
AstraZeneca R&D

Locations: Sweden
Research Site
Lund, Sweden

Research Site
Molndal, Sweden

Research Site
Stockholm, Sweden

United Kingdom
Research Site
Nottingham, United Kingdom

United States, California
Research Site
Newport Beach, California, United States

United States, Georgia
Research Site
Atlanta, Georgia, United States

Research Site
Morrow, Georgia, United States

United States, Kansas
Research Site
Overland Park, Kansas, United States

United States, North Carolina
Research Site
Charlotte, North Carolina, United States

Research Site
Durham, North Carolina, United States

United States, Tennessee
Research Site
Memphis, Tennessee, United States

## References

Citations:

Links:

Study Data/Documents:

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# Study Results

## Participant Flow

| | |
|---|---|
| Recruitment Details | This multicenter study was conducted in 19 centers in the US, UK, and Sweden between 13 December 2010 and 06 November 2012. A total of 117 patients were screened in the study and of these, 50 were randomized into the double-blind treatment period. |
| Pre-Assignment Details | Diagnosis of intra-ocular hypertension (raised IOP), or POAG, with IOP >20 mmHg and =<36 mmHg, and currently prescribed a stable dose of one anti-glaucoma medication that began at least 30 days prior to the screening visit or a diagnosis of intra-ocular hypertension, defined as an IOP >22 mmHg and =<36 mmHg while not on anti-glaucoma medication. |

Reporting Groups

| | Description |
|---|---|
| Placebo OD | Placebo once daily |
| AZD4017 200 mg OD | AZD4017 200 mg once daily |
| Placebo BID | Placebo twice daily |
| AZD4017 400 mg BID | AZD4017 400 mg twice daily |

Overall Study

| | Placebo OD | AZD4017 200 mg OD | Placebo BID | AZD4017 400 mg BID |
|---|---|---|---|---|
| Started | 6 [1] | 7 [1] | 18 [1] | 19 [1] |

| | Placebo OD | AZD4017 200 mg OD | Placebo BID | AZD4017 400 mg BID |
|---|---|---|---|---|
| Received Treatment | 6 | 7 | 18 | 19 |
| Completed Treatment | 4 | 7 | 15 | 18 |
| Completed | 4 [2] | 7 [2] | 15 [2] | 18 [2] |
| Not Completed | 2 | 0 | 3 | 1 |
| Eligibility criteria not fulfilled | 0 | 0 | 1 | 1 |
| Condition under investigation worsened | 2 | 0 | 0 | 0 |
| Lost to Follow-up | 0 | 0 | 1 | 0 |
| Reason given as Other | 0 | 0 | 1 | 0 |

[1] Randomized
[2] Completed study

## Baseline Characteristics

Reporting Groups

| | Description |
|---|---|
| Placebo OD | Placebo once daily |
| AZD4017 200 mg OD | AZD4017 200 mg once daily |
| Placebo BID | Placebo twice daily |
| AZD4017 400 mg BID | AZD4017 400 mg twice daily |

Baseline Measures

| | Placebo OD | AZD4017 200 mg OD | Placebo BID | AZD4017 400 mg BID | Total |
|---|---|---|---|---|---|
| Number of Participants | 6 | 7 | 18 | 19 | 50 |
| Age, Continuous<br>[units: Years]<br>Mean (Standard Deviation) | 63 (6.7) | 63 (8.7) | 57 (15.1) | 65 (10.1) | 61 (11.9) |
| Age, Customized<br>[units: Participants] | | | | | |
| <50 years | 0 | 1 | 5 | 2 | 8 |

| | Placebo OD | AZD4017 200 mg OD | Placebo BID | AZD4017 400 mg BID | Total |
|---|---|---|---|---|---|
| >=50-<65 years | 3 | 4 | 6 | 5 | 18 |
| >=65 years | 3 | 2 | 7 | 12 | 24 |
| Gender, Male/Female [units: Participants] | | | | | |
| Female | 2 | 3 | 9 | 11 | 25 |
| Male | 4 | 4 | 9 | 8 | 25 |
| Race/Ethnicity, Customized [units: Participants] | | | | | |
| American Indian or Alaska Native | 0 | 0 | 0 | 0 | 0 |
| Asian | 0 | 0 | 1 | 0 | 1 |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 0 | 0 | 0 |
| Black or African American | 0 | 0 | 5 | 5 | 10 |
| White | 6 | 7 | 12 | 14 | 39 |
| Other | 0 | 0 | 0 | 0 | 0 |
| Missing | 0 | 0 | 0 | 0 | 0 |
| Region of Enrollment [units: Participants] | | | | | |
| United Kingdom | 2 | 4 | 0 | 0 | 6 |
| Sweden | 4 | 3 | 0 | 0 | 7 |
| United States | 0 | 0 | 18 | 19 | 37 |
| Stratification factor [units: Participants] | | | | | |
| Add-on to intra-ocular pressure medication | 0 | 1 | 8 | 9 | 18 |
| Not on intra-ocular pressure medication | 6 | 6 | 10 | 10 | 32 |

# Outcome Measures

1. Primary Outcome Measure:

| | |
|---|---|
| Measure Title | Percentage Change in Mean Intra-ocular Pressure Compared With Baseline After 4 Weeks Treatment |
| Measure Description | |
| Time Frame | Baseline to 4 weeks |
| Safety Issue? | No |

Analysis Population Description
Efficacy analysis set

Reporting Groups

| | Description |
|---|---|
| Placebo OD | Placebo once daily |
| AZD4017 200 mg OD | AZD4017 200 mg once daily |
| Placebo BID | Placebo twice daily |
| AZD4017 400 mg BID | AZD4017 400 mg twice daily |

Measured Values

| | Placebo OD | AZD4017 200 mg OD | Placebo BID | AZD4017 400 mg BID |
|---|---|---|---|---|
| Number of Participants Analyzed | 6 | 7 | 16 | 19 |
| Percentage Change in Mean Intra-ocular Pressure Compared With Baseline After 4 Weeks Treatment<br>[units: Percentage change]<br>Least Squares Mean (95% Confidence Interval) | 0.8 (-15.6 to 17.3) | -0.4 (-13.8 to 13.0) | -8.1 (-13.3 to -2.9) | -11.0 (-15.8 to -6.2) |

Statistical Analysis 1 for Percentage Change in Mean Intra-ocular Pressure Compared With Baseline After 4 Weeks Treatment

| | | |
|---|---|---|
| Statistical Analysis Overview | Comparison Groups | Placebo OD, AZD4017 200 mg OD |
| | Comments | [Not specified] |
| | Non-Inferiority or Equivalence Analysis? | No |
| | Comments | [Not specified] |

| | | |
|---|---|---|
| Statistical Test of Hypothesis | P-Value | 0.822 |
| | Comments | [Not specified] |
| | Method | Mixed Models Analysis |
| | Comments | [Not specified] |

| | | |
|---|---|---|
| Method of Estimation | Estimation Parameter | Mean Difference (Final Values) |
| | Estimated Value | -1.3 |
| | Confidence Interval | (2-Sided) 95%<br>-15.2 to 12.6 |
| | Parameter Dispersion | Type: Standard Error of the mean<br>Value: 5.352 |
| | Estimation Comments | Difference is (AZD4017 200 mg OD - Placebo OD) |

Statistical Analysis 2 for Percentage Change in Mean Intra-ocular Pressure Compared With Baseline After 4 Weeks Treatment

| | | |
|---|---|---|
| Statistical Analysis Overview | Comparison Groups | Placebo BID, AZD4017 400 mg BID |
| | Comments | [Not specified] |
| | Non-Inferiority or Equivalence Analysis? | No |
| | Comments | [Not specified] |

| | | |
|---|---|---|
| Statistical Test of Hypothesis | P-Value | 0.413 |
| | Comments | [Not specified] |
| | Method | Mixed Models Analysis |
| | Comments | [Not specified] |

| | | |
|---|---|---|
| Method of Estimation | Estimation Parameter | Mean Difference (Final Values) |
| | Estimated Value | -2.9 |
| | Confidence Interval | (2-Sided) 95%<br>-10.1 to 4.3 |
| | Parameter Dispersion | Type: Standard Error of the mean<br>Value: 3.516 |
| | Estimation Comments | Difference is (AZD4017 400 mg BID - Placebo BID) |

2. Secondary Outcome Measure:

| | |
|---|---|
| Measure Title | Clinically Relevant Change in Intra-ocular Pressure After 4 Weeks of Treatment |
| Measure Description | |
| Time Frame | Baseline to 4 weeks |
| Safety Issue? | No |

Analysis Population Description
Efficacy analysis set

Reporting Groups

| | Description |
|---|---|
| Placebo OD | Placebo once daily |
| AZD4017 200 mg OD | AZD4017 200 mg once daily |
| Placebo BID | Placebo twice daily |
| AZD4017 400 mg BID | AZD4017 400 mg twice daily |

Measured Values

| | Placebo OD | AZD4017 200 mg OD | Placebo BID | AZD4017 400 mg BID |
|---|---|---|---|---|
| Number of Participants Analyzed | 6 | 7 | 18 | 19 |
| Clinically Relevant Change in Intra-ocular Pressure After 4 Weeks of Treatment [units: Participants] | | | | |
| >= 20% decrease in intra-ocular pressure | 0 | 0 | 1 | 4 |
| >= 30% decrease in intra-ocular pressure | 0 | 0 | 0 | 0 |

3. Secondary Outcome Measure:

| | |
|---|---|
| Measure Title | Change in Mean Intra-ocular Pressure Compared With Baseline After 4 Weeks Treatment |
| Measure Description | |
| Time Frame | Baseline to 4 weeks |
| Safety Issue? | No |

Analysis Population Description
Efficacy analysis set

Reporting Groups

| | Description |
|---|---|
| Placebo OD | Placebo once daily |
| AZD4017 200 mg OD | AZD4017 200 mg once daily |
| Placebo BID | Placebo twice daily |
| AZD4017 400 mg BID | AZD4017 400 mg twice daily |

Measured Values

| | Placebo OD | AZD4017 200 mg OD | Placebo BID | AZD4017 400 mg BID |
|---|---|---|---|---|
| Number of Participants Analyzed | 6 | 7 | 16 | 19 |
| Change in Mean Intra-ocular Pressure Compared With Baseline After 4 Weeks Treatment<br>[units: mmHg]<br>Least Squares Mean (95% Confidence Interval) | 0.1 (-4.8 to 4.9) | -0.4 (-4.4 to 3.5) | -1.9 (-3.3 to -0.6) | -2.6 (-3.8 to -1.3) |

Statistical Analysis 1 for Change in Mean Intra-ocular Pressure Compared With Baseline After 4 Weeks Treatment

| | | |
|---|---|---|
| Statistical Analysis Overview | Comparison Groups | Placebo OD, AZD4017 200 mg OD |
| | Comments | [Not specified] |
| | Non-Inferiority or Equivalence Analysis? | No |
| | Comments | [Not specified] |

| | | |
|---|---|---|
| Statistical Test of Hypothesis | P-Value | 0.758 |
| | Comments | [Not specified] |
| | Method | Mixed Models Analysis |
| | Comments | [Not specified] |

| | | |
|---|---|---|
| Method of Estimation | Estimation Parameter | Mean Difference (Final Values) |
| | Estimated Value | -0.5 |
| | Confidence Interval | (2-Sided) 95% |

| | | |
|---|---|---|
| | | -4.8 to 3.7 |
| | Parameter Dispersion | Type: Standard Error of the mean<br>Value: 1.570 |
| | Estimation Comments | Difference is (AZD4017 200 mg OD - Placebo OD) |

Statistical Analysis 2 for Change in Mean Intra-ocular Pressure Compared With Baseline After 4 Weeks Treatment

| | | |
|---|---|---|
| Statistical Analysis Overview | Comparison Groups | Placebo BID, AZD4017 400 mg BID |
| | Comments | [Not specified] |
| | Non-Inferiority or Equivalence Analysis? | No |
| | Comments | [Not specified] |

| | | |
|---|---|---|
| Statistical Test of Hypothesis | P-Value | 0.467 |
| | Comments | [Not specified] |
| | Method | Mixed Models Analysis |
| | Comments | [Not specified] |

| | | |
|---|---|---|
| Method of Estimation | Estimation Parameter | Mean Difference (Final Values) |
| | Estimated Value | -0.7 |
| | Confidence Interval | (2-Sided) 95%<br>-2.5 to 1.2 |
| | Parameter Dispersion | Type: Standard Error of the mean<br>Value: 0.909 |
| | Estimation Comments | Difference is (AZD4017 400 mg BID - Placebo BID) |

## Reported Adverse Events

| | |
|---|---|
| Time Frame | 4-week treatment period. |
| Additional Description | All patients were required to return for a mandatory follow-up visit (Visit 8) between 14 and 21 days, inclusive, after the last dose of study medication. Any ongoing adverse events (AEs) at the follow-up visit were followed until resolution, until the AE stabilized, until it was otherwise explained, or until the patient was lost to follow-up. |

Reporting Groups

| | Description |
|---|---|
| Placebo OD | Placebo once daily |
| AZD4017 200 mg OD | AZD4017 200 mg once daily |
| Placebo BID | Placebo twice daily |
| AZD4017 400 mg BID | AZD4017 400 mg twice daily |

Serious Adverse Events

| | Placebo OD | | AZD4017 200 mg OD | | Placebo BID | | AZD4017 400 mg BID | |
|---|---|---|---|---|---|---|---|---|
| | Affected/ At Risk (%) | # Events | Affected/ At Risk (%) | # Events | Affected/ At Risk (%) | # Events | Affected/ At Risk (%) | # Events |
| Total | 0/6 (0%) | | 0/7 (0%) | | 0/18 (0%) | | 0/19 (0%) | |

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 1%

| | Placebo OD | | AZD4017 200 mg OD | | Placebo BID | | AZD4017 400 mg BID | |
|---|---|---|---|---|---|---|---|---|
| | Affected/ At Risk (%) | # Events | Affected/ At Risk (%) | # Events | Affected/ At Risk (%) | # Events | Affected/ At Risk (%) | # Events |
| Total | 5/6 (83.33%) | | 3/7 (42.86%) | | 5/18 (27.78%) | | 7/19 (36.84%) | |
| Eye disorders | | | | | | | | |
| BLEPHARITIS [A] † | 1/6 (16.67%) | 1 | 0/7 (0%) | 0 | 0/18 (0%) | 0 | 0/19 (0%) | 0 |
| CONJUNCTIVAL HAEMORRHAGE [A] † | 0/6 (0%) | 0 | 0/7 (0%) | 0 | 0/18 (0%) | 0 | 1/19 (5.26%) | 1 |
| CONJUNCTIVAL HYPERAEMIA [A] † | 0/6 (0%) | 0 | 0/7 (0%) | 0 | 0/18 (0%) | 0 | 1/19 (5.26%) | 1 |
| DELLEN [A] † | 0/6 (0%) | 0 | 0/7 (0%) | 0 | 1/18 (5.56%) | 1 | 0/19 (0%) | 0 |
| DRY EYE [A] † | 1/6 (16.67%) | 1 | 0/7 (0%) | 0 | 0/18 (0%) | 0 | 0/19 (0%) | 0 |

| | Placebo OD | | AZD4017 200 mg OD | | Placebo BID | | AZD4017 400 mg BID | |
|---|---|---|---|---|---|---|---|---|
| | Affected/ At Risk (%) | # Events | Affected/ At Risk (%) | # Events | Affected/ At Risk (%) | # Events | Affected/ At Risk (%) | # Events |
| EYE PAIN [A] † | 0/6 (0%) | 0 | 1/7 (14.29%) | 1 | 0/18 (0%) | 0 | 0/19 (0%) | 0 |
| PHOTOPHOBIA [A] † | 0/6 (0%) | 0 | 0/7 (0%) | 0 | 0/18 (0%) | 0 | 1/19 (5.26%) | 1 |
| VITREOUS DETACHMENT [A] † | 0/6 (0%) | 0 | 0/7 (0%) | 0 | 1/18 (5.56%) | 1 | 0/19 (0%) | 0 |
| Gastrointestinal disorders | | | | | | | | |
| ABDOMINAL PAIN [A] † | 0/6 (0%) | 0 | 0/7 (0%) | 0 | 1/18 (5.56%) | 1 | 1/19 (5.26%) | 1 |
| DRY MOUTH [A] † | 0/6 (0%) | 0 | 0/7 (0%) | 0 | 1/18 (5.56%) | 1 | 0/19 (0%) | 0 |
| DYSPEPSIA [A] † | 0/6 (0%) | 0 | 0/7 (0%) | 0 | 0/18 (0%) | 0 | 1/19 (5.26%) | 1 |
| LIP PRURITUS [A] † | 0/6 (0%) | 0 | 0/7 (0%) | 0 | 1/18 (5.56%) | 1 | 0/19 (0%) | 0 |
| VOMITING [A] † | 0/6 (0%) | 0 | 2/7 (28.57%) | 2 | 0/18 (0%) | 0 | 0/19 (0%) | 0 |
| General disorders | | | | | | | | |
| FATIGUE [A] † | 0/6 (0%) | 0 | 0/7 (0%) | 0 | 1/18 (5.56%) | 1 | 1/19 (5.26%) | 1 |
| Infections and infestations | | | | | | | | |
| ASYMPTOMATIC BACTERIURIA [A] † | 0/6 (0%) | 0 | 1/7 (14.29%) | 1 | 0/18 (0%) | 0 | 0/19 (0%) | 0 |
| CONJUNCTIVITIS INFECTIVE [A] † | 1/6 (16.67%) | 1 | 0/7 (0%) | 0 | 0/18 (0%) | 0 | 0/19 (0%) | 0 |
| GASTROINTESTINAL INFECTION [A] † | 0/6 (0%) | 0 | 1/7 (14.29%) | 1 | 0/18 (0%) | 0 | 0/19 (0%) | 0 |
| INFECTED BITES [A] † | 0/6 (0%) | 0 | 0/7 (0%) | 0 | 0/18 (0%) | 0 | 1/19 (5.26%) | 1 |

| | Placebo OD | | AZD4017 200 mg OD | | Placebo BID | | AZD4017 400 mg BID | |
|---|---|---|---|---|---|---|---|---|
| | Affected/ At Risk (%) | # Events | Affected/ At Risk (%) | # Events | Affected/ At Risk (%) | # Events | Affected/ At Risk (%) | # Events |
| NASOPHARYNGITIS [A] † | 1/6 (16.67%) | 1 | 0/7 (0%) | 0 | 0/18 (0%) | 0 | 0/19 (0%) | 0 |
| URINARY TRACT INFECTION [A] † | 0/6 (0%) | 0 | 0/7 (0%) | 0 | 1/18 (5.56%) | 1 | 0/19 (0%) | 0 |
| Injury, poisoning and procedural complications | | | | | | | | |
| JOINT INJURY [A] † | 0/6 (0%) | 0 | 0/7 (0%) | 0 | 0/18 (0%) | 0 | 1/19 (5.26%) | 1 |
| Investigations | | | | | | | | |
| INTRAOCULAR PRESSURE INCREASED [A] † | 2/6 (33.33%) | 2 | 0/7 (0%) | 0 | 0/18 (0%) | 0 | 0/19 (0%) | 0 |
| Musculoskeletal and connective tissue disorders | | | | | | | | |
| SENSATION OF HEAVINESS [A] † | 0/6 (0%) | 0 | 1/7 (14.29%) | 1 | 0/18 (0%) | 0 | 0/19 (0%) | 0 |
| Nervous system disorders | | | | | | | | |
| BALANCE DISORDER [A] † | 0/6 (0%) | 0 | 0/7 (0%) | 0 | 0/18 (0%) | 0 | 1/19 (5.26%) | 1 |
| HEADACHE [A] † | 0/6 (0%) | 0 | 0/7 (0%) | 0 | 0/18 (0%) | 0 | 1/19 (5.26%) | 1 |
| PARAESTHESIA [A] † | 0/6 (0%) | 0 | 1/7 (14.29%) | 1 | 0/18 (0%) | 0 | 0/19 (0%) | 0 |
| PRESYNCOPE [A] † | 0/6 (0%) | 0 | 1/7 (14.29%) | 1 | 0/18 (0%) | 0 | 0/19 (0%) | 0 |
| Renal and urinary disorders | | | | | | | | |
| POLLAKIURIA [A] † | 0/6 (0%) | 0 | 0/7 (0%) | 0 | 0/18 (0%) | 0 | 1/19 (5.26%) | 1 |
| Respiratory, thoracic and mediastinal disorders | | | | | | | | |
| THROAT IRRITATION [A] † | 0/6 (0%) | 0 | 0/7 (0%) | 0 | 1/18 (5.56%) | 1 | 0/19 (0%) | 0 |
| Vascular disorders | | | | | | | | |

| | Placebo OD | | AZD4017 200 mg OD | | Placebo BID | | AZD4017 400 mg BID | |
|---|---|---|---|---|---|---|---|---|
| | Affected/ At Risk (%) | # Events | Affected/ At Risk (%) | # Events | Affected/ At Risk (%) | # Events | Affected/ At Risk (%) | # Events |
| FLUSHING [A] † | 0/6 (0%) | 0 | 0/7 (0%) | 0 | 1/18 (5.56%) | 1 | 0/19 (0%) | 0 |

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA Version 15.1

## 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.

The Sponsor recognises that the Trust and Investigator have a responsibility under the Research Governance Framework for Health and Social Care to ensure that results of scientific interest arising from the Clinical Trial are appropriately published and disseminated. Such data will be submitted to the Sponsor for review and comment prior to publication. The Trust agrees, and shall ensure that the Investigator agrees, that all reasonable comments made by the Sponsor will be incorporated.

Results Point of Contact:

Name/Official Title: Stuart McIntosh
Organization: AstraZeneca
Phone:
Email: ClinicalTrialTransparency@astrazeneca.com