ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 08/14/2012

ClinicalTrials.gov ID: NCT00769119

Study Identification

Unique Protocol ID:	D0520C00010
Brief Title:	A Phase II , Placebo-controlled Study to Assess Efficacy of 28 Day Oral AZD9668 in Patients With Bronchiectasis (NEPAL)
Official Title:	A Phase II, Randomised, Double-blind, Placebo-controlled, Parallel Group Study to Assess the Efficacy of 28 Day Oral Administration of AZD9668 in Patients With Bronchiectasis
Secondary IDs:	

Study Status

Record Verification:	August 2012
Overall Status:	Completed
Study Start:	September 2008
Primary Completion:	April 2009 [Actual]
Study Completion:	April 2009 [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: 18th August 08 Board Name: University of British Columbia, Clinical Research Ethics Board Office Board Affiliation: University of British Columbia Phone: 604-875-4111 Email:
Data Monitoring?:	No
Plan to Share Data?:	
Oversight Authorities:	Canada: Health Canada United Kingdom: Medicines and Healthcare Products Regulatory Agency

Study Description

Brief Summary:	The purpose of this study is to investigate if treatment with AZD9668 for 28 days is effective in treating Bronchiectasis (Brx) and if so how it compares to placebo (a substance which does not have any action).
Detailed Description:	

Conditions

Conditions:	Bronchiectasis
Keywords:	bronchiectasis Phase II

Study Design

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

Enrollment: 38 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: AZD9668 active treatment	Drug: AZD9668 2 x 30 mg, oral tablet, twice daily for 28 days
Placebo Comparator: AZD9668 placebo treatment	Drug: Placebo 2 x Matched placebo, oral tablet, twice daily for 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:

- Female of non child bearing potential
- Clinical diagnosis of bronchiectasis
- Be sputum producers, with history of chronic expectoration on most days

Exclusion Criteria:

- Concomitant diagnosis of pulmonary disease other than bronchiectasis or COPD
- FEV1 of <30% of predicted normal

Contacts/Locations

Study Officials: Stockley, Prof
Study Principal Investigator
Queen Elizabeth Hospital, Birmingham, England

Carin Jorup
Study Director

AstraZeneca R&D Lund

Locations: United Kingdom
Research Site
Birmingham, United Kingdom

Research Site
New Castle, United Kingdom

Research Site
Cambridge, United Kingdom

Research Site
London, United Kingdom

Canada, Quebec
Research Site
Chemin Sainte-Foy, Quebec, Canada

Canada
Research Site
Vancouver, Canada

Research Site
Calgary, Canada

Research Site
Montreal, Canada

Research Site
Ontario, Canada

References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Recruitment Details	First patient enrolled 25 September 2008. Last patient completed 20 April 2009. Study conducted at 6 centres in Canada and 4 centres in the UK.

Reporting Groups

	Description
AZD9668	AZD9668, 2 x 30 mg twice daily (bid)
Placebo	Placebo, 2 tablets twice daily (bid)

Overall Study

	AZD9668	Placebo
Started	22	16
Completed	20	13
Not Completed	2	3
Voluntary discontinuation	0	2
Adverse Event	1	1
Disallowed medication	1	0

Baseline Characteristics

Reporting Groups

	Description
AZD9668	AZD9668, 2 x 30 mg twice daily (bid)
Placebo	Placebo, 2 tablets twice daily (bid)

Baseline Measures

	AZD9668	Placebo	Total
Number of Participants	22	16	38
Age, Continuous [units: years] Median (Full Range)	61 (42 to 79)	62 (54 to 73)	62 (42 to 79)

	AZD9668	Placebo	Total
Gender, Male/Female [units: Participants]			
Female	9	11	20
Male	13	5	18

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Ratio of Absolute Neutrophil Count at End of Treatment Compared to Baseline
Measure Description	Ratio of the mean of 3 visits at the end of the treatment period to the mean of the 3 baseline visits
Time Frame	End of treatment values from 3 visits (day 21 to 28) and baseline values from 3 visits.
Safety Issue?	No

Analysis Population Description

The efficacy analysis set for each outcome measure includes those patients who received at least one dose of investigational product and for whom a baseline and at least one post-randomisation measurement is available for that outcome measure. Patients were analysed by to randomised treatment in accordance with the intention to treat principle.

Reporting Groups

	Description
AZD9668	AZD9668, 2 x 30 mg twice daily (bid)
Placebo	Placebo, 2 tablets twice daily (bid)

Measured Values

	AZD9668	Placebo
Number of Participants Analyzed	18	10
Ratio of Absolute Neutrophil Count at End of Treatment Compared to Baseline [units: ratio] Least Squares Mean (95% Confidence Interval)	1.08 (0.60 to 1.72)	1.01 (0.73 to 1.60)

2. Primary Outcome Measure:

Measure Title	Ratio of the Percentage Neutrophil Count at End of Treatment Compared to Baseline

Measure Description	Ratio of the mean of 3 visits at the end of the treatment period to the mean of the 3 baseline visits
Time Frame	End of treatment values from 3 visits (day 21 to 28) and baseline values from 3 visits.
Safety Issue?	No

Analysis Population Description

The efficacy analysis set for each outcome measure includes those patients who received at least one dose of investigational product and for whom a baseline and at least one post-randomisation measurement is available for that outcome measure. Patients were analysed by to randomised treatment in accordance with the intention to treat principle.

Reporting Groups

	Description
AZD9668	AZD9668, 2 x 30 mg twice daily (bid)
Placebo	Placebo, 2 tablets twice daily (bid)

Measured Values

	AZD9668	Placebo
Number of Participants Analyzed	18	10
Ratio of the Percentage Neutrophil Count at End of Treatment Compared to Baseline [units: ratio] Least Squares Mean (95% Confidence Interval)	1.12 (1.02 to 1.21)	1.04 (0.92 to 1.16)

3. Primary Outcome Measure:

Measure Title	24-hour Sputum Weight(g)
Measure Description	Sputum weight (g) collected during 24 hour periods.Change from Baseline to day 28
Time Frame	Baseline and day 28
Safety Issue?	No

Analysis Population Description

The efficacy analysis set for each outcome measure includes those patients who received at least one dose of investigational product and for whom a baseline and at least one post-randomisation measurement is available for that outcome measure. Patients were analysed by to randomised treatment in accordance with the intention to treat principle.

Reporting Groups

	Description
AZD9668	AZD9668, 2 x 30 mg twice daily (bid)
Placebo	Placebo, 2 tablets twice daily (bid)

Measured Values

	AZD9668	Placebo
Number of Participants Analyzed	20	13
24-hour Sputum Weight(g) [units: g] Least Squares Mean (Standard Error)	-0.15 (4.376)	-5.37 (3.455)

4. Primary Outcome Measure:

Measure Title	Slow Vital Capacity (SVC)
Measure Description	Slow Vital Capacity (L) as a measure of lung function.Change from baseline to day 28
Time Frame	Baseline and day 28
Safety Issue?	No

Analysis Population Description

The efficacy analysis set for each outcome measure includes those patients who received at least one dose of investigational product and for whom a baseline and at least one post-randomisation measurement is available for that outcome measure. Patients were analysed by to randomised treatment in accordance with the intention to treat principle.

Reporting Groups

	Description
AZD9668	AZD9668, 2 x 30 mg twice daily (bid)
Placebo	Placebo, 2 tablets twice daily (bid)

Measured Values

	AZD9668	Placebo
Number of Participants Analyzed	20	13
Slow Vital Capacity (SVC) [units: L] Least Squares Mean (Standard Error)	0.07 (0.045)	-0.07 (0.057)

5. Primary Outcome Measure:

Measure Title	Forced Expiratory Volume in 1 Second (FEV1)
Measure Description	Forced Expiratory Volume in 1 Second (L) as a measure of lung function.Change from baseline to day 28
Time Frame	Baseline and day 28
Safety Issue?	No

Analysis Population Description

The efficacy analysis set for each outcome measure includes those patients who received at least one dose of investigational product and for whom a baseline and at least one post-randomisation measurement is available for that outcome measure. Patients were analysed by to randomised treatment in accordance with the intention to treat principle.

Reporting Groups

	Description
AZD9668	AZD9668, 2 x 30 mg twice daily (bid)
Placebo	Placebo, 2 tablets twice daily (bid)

Measured Values

	AZD9668	Placebo
Number of Participants Analyzed	20	13
Forced Expiratory Volume in 1 Second (FEV1) [units: L] Least Squares Mean (Standard Error)	0.06 (0.021)	-0.04 (0.026)

6. Primary Outcome Measure:

Measure Title	Forced Vital Capacity (FVC)
Measure Description	Forced Vital Capacity (L) as a measure of lung function.Change from baseline to day 28
Time Frame	Baseline and day 28
Safety Issue?	No

Analysis Population Description

The efficacy analysis set for each outcome measure includes those patients who received at least one dose of investigational product and for whom a baseline and at least one post-randomisation measurement is available for that outcome measure. Patients were analysed by to randomised treatment in accordance with the intention to treat principle.

Reporting Groups

	Description
AZD9668	AZD9668, 2 x 30 mg twice daily (bid)
Placebo	Placebo, 2 tablets twice daily (bid)

Measured Values

	AZD9668	Placebo
Number of Participants Analyzed	20	13
Forced Vital Capacity (FVC) [units: L] Least Squares Mean (Standard Error)	0.03 (0.048)	0.00 (0.061)

7. Primary Outcome Measure:

Measure Title	Forced Expiratory Flow Between 25 and 75% of Forced Vital Capacity (FEF25-75%)
Measure Description	FEF25-75% as a measure of lung function.Change from baseline to day 28
Time Frame	Baseline and day 28
Safety Issue?	No

Analysis Population Description

The efficacy analysis set for each outcome measure includes those patients who received at least one dose of investigational product and for whom a baseline and at least one post-randomisation measurement is available for that outcome measure. Patients were analysed by to randomised treatment in accordance with the intention to treat principle.

Reporting Groups

	Description
AZD9668	AZD9668, 2 x 30 mg twice daily (bid)
Placebo	Placebo, 2 tablets twice daily (bid)

Measured Values

	AZD9668	Placebo
Number of Participants Analyzed	20	13
Forced Expiratory Flow Between 25 and 75% of Forced Vital Capacity (FEF25-75%) [units: L/s] Least Squares Mean (Standard Error)	0.08 (0.031)	0.01 (0.038)

8. Primary Outcome Measure:

Measure Title	Morning Peak Expiratory Flow (PEF)
Measure Description	Morning Peak Expiratory Flow (L/min) as a measure of lung function.Change from mean baseline value to mean of the last 7 days on treatment
Time Frame	Last 7 days on treatment
Safety Issue?	No

Analysis Population Description

The efficacy analysis set for each outcome measure includes those patients who received at least one dose of investigational product and for whom a baseline and at least one post-randomisation measurement is available for that outcome measure. Patients were analysed by to randomised treatment in accordance with the intention to treat principle.

Reporting Groups

	Description
AZD9668	AZD9668, 2 x 30 mg twice daily (bid)
Placebo	Placebo, 2 tablets twice daily (bid)

Measured Values

	AZD9668	Placebo
Number of Participants Analyzed	21	16
Morning Peak Expiratory Flow (PEF) [units: L/min] Least Squares Mean (Standard Error)	4.06 (6.168)	-4.98 (7.174)

9. Primary Outcome Measure:

Measure Title	Evening Peak Expiratory Flow (PEF)
Measure Description	Evening Peak Expiratory Flow (L/min) as a measure of lung function.Change from mean baseline value to mean of the last 7 days on treatment
Time Frame	Last 7 days on treatment
Safety Issue?	No

Analysis Population Description

The efficacy analysis set for each outcome measure includes those patients who received at least one dose of investigational product and for whom a baseline and at least one post-randomisation measurement is available for that outcome measure. Patients were analysed by to randomised treatment in accordance with the intention to treat principle.

Reporting Groups

	Description
AZD9668	AZD9668, 2 x 30 mg twice daily (bid)
Placebo	Placebo, 2 tablets twice daily (bid)

Measured Values

	AZD9668	Placebo
Number of Participants Analyzed	21	16
Evening Peak Expiratory Flow (PEF) [units: L/min] Least Squares Mean (Standard Error)	4.56 (6.352)	-1.15 (7.399)

10. Primary Outcome Measure:

Measure Title	Bronkotest Diary Card Signs and Symptoms
Measure Description	The Bronkotest diary card includes 8 questions on signs and symptoms. Symptom scores were recorded for night-time symptoms, breathing, sputum colour, sputum amount, sputum type, wellbeing, and cough, generally scored on a scale from 0 (no symptoms) to 4 (worst symptoms). ANOVA models were fitted to compare the change from baseline between AZD9668 and placebo for each question separately, with a p-value of 0.1 considered statistically significant. The number of number of these 8 measures with significant differences is reported.
Time Frame	Last 7 days on treatment
Safety Issue?	No

Analysis Population Description

The efficacy analysis set for each outcome measure includes those patients who received at least one dose of investigational product and for whom a baseline and at least one post-randomisation measurement is available for that outcome measure. Patients were analysed by to randomised treatment in accordance with the intention to treat principle.

Reporting Groups

	Description
AZD9668	AZD9668, 2 x 30 mg twice daily (bid)
Placebo	Placebo, 2 tablets twice daily (bid)

Measured Values

	AZD9668	Placebo
Number of Participants Analyzed	21	16
Bronkotest Diary Card Signs and Symptoms [units: events]	0	0

11. Primary Outcome Measure:

Measure Title	St George's Respiratory Questionnaire for COPD Patients (SGRQ-C)
Measure Description	SGRQ total score shows the impact of COPD on patient's health status, and expressed as a percentage of impairment with scale from 0 (best health status) to 100 (worst possible status). Change from baseline to day 28.
Time Frame	Baseline and day 28
Safety Issue?	No

Analysis Population Description

The efficacy analysis set for each outcome measure includes those patients who received at least one dose of investigational product and for whom a baseline and at least one post-randomisation measurement is available for that outcome measure. Patients were analysed by to randomised treatment in accordance with the intention to treat principle.

Reporting Groups

	Description
AZD9668	AZD9668, 2 x 30 mg twice daily (bid)
Placebo	Placebo, 2 tablets twice daily (bid)

Measured Values

	AZD9668	Placebo
Number of Participants Analyzed	19	13
St George's Respiratory Questionnaire for COPD Patients (SGRQ-C) [units: Scores on a scale] Least Squares Mean (Standard Error)	-7.39 (3.764)	-1.137 (4.608)

12. Secondary Outcome Measure:

Measure Title	Ratio of Tumour Necrosis Factor Alpha (TNF α) at End of Treatment Compared to Baseline
Measure Description	Ratio of the mean of 3 visits at the end of the treatment period to the mean of the 3 baseline visits
Time Frame	End of treatment values from 3 visits (day 21 to 28) and baseline values from 3 visits.
Safety Issue?	No

Analysis Population Description

The efficacy analysis set for each outcome measure includes those patients who received at least one dose of investigational product and for whom a baseline and at least one post-randomisation measurement is available for that outcome measure. Patients were analysed by to randomised treatment in accordance with the intention to treat principle.

Reporting Groups

	Description
AZD9668	AZD9668, 2 x 30 mg twice daily (bid)
Placebo	Placebo, 2 tablets twice daily (bid)

Measured Values

	AZD9668	Placebo
Number of Participants Analyzed	20	12
Ratio of Tumour Necrosis Factor Alpha (TNF α) at End of Treatment Compared to Baseline [units: ratio] Least Squares Mean (95% Confidence Interval)	0.93 (0.66 to 1.30)	1.00 (0.64 to 1.55)

13. Secondary Outcome Measure:

Measure Title	Ratio of Interleukin 6 (IL-6) at End of Treatment Compared to Baseline
Measure Description	Ratio of the mean of 3 visits at the end of the treatment period to the mean of the 3 baseline visits
Time Frame	End of treatment values from 3 visits (day 21 to 28) and baseline values from 3 visits.
Safety Issue?	No

Analysis Population Description

The efficacy analysis set for each outcome measure includes those patients who received at least one dose of investigational product and for whom a baseline and at least one post-randomisation measurement is available for that outcome measure. Patients were analysed by to randomised treatment in accordance with the intention to treat principle.

Reporting Groups

	Description
AZD9668	AZD9668, 2 x 30 mg twice daily (bid)
Placebo	Placebo, 2 tablets twice daily (bid)

Measured Values

	AZD9668	Placebo
Number of Participants Analyzed	20	12
Ratio of Interleukin 6 (IL-6) at End of Treatment Compared to Baseline [units: ratio] Least Squares Mean (95% Confidence Interval)	0.70 (0.58 to 0.86)	0.98 (0.75 to 1.28)

14. Secondary Outcome Measure:

Measure Title	Ratio of Interleukin 1 Beta (IL-1β) at End of Treatment Compared to Baseline
Measure Description	Ratio of the mean of 3 visits at the end of the treatment period to the mean of the 3 baseline visits
Time Frame	End of treatment values from 3 visits (day 21 to 28) and baseline values from 3 visits.
Safety Issue?	No

Analysis Population Description

The efficacy analysis set for each outcome measure includes those patients who received at least one dose of investigational product and for whom a baseline and at least one post-randomisation measurement is available for that outcome measure. Patients were analysed by to randomised treatment in accordance with the intention to treat principle.

Reporting Groups

	Description
AZD9668	AZD9668, 2 x 30 mg twice daily (bid)
Placebo	Placebo, 2 tablets twice daily (bid)

Measured Values

	AZD9668	Placebo
Number of Participants Analyzed	20	11
Ratio of Interleukin 1 Beta (IL-1β) at End of Treatment Compared to Baseline [units: ratio] Least Squares Mean (95% Confidence Interval)	0.74 (0.52 to 1.07)	0.93 (0.57 to 1.53)

15. Secondary Outcome Measure:

Measure Title	Ratio of Regulated on Activation, Normal T Cell Expressed and Secreted (RANTES) at End of Treatment Compared to Baseline
Measure Description	Ratio of the mean of 3 visits at the end of the treatment period to the mean of the 3 baseline visits
Time Frame	End of treatment values from 3 visits (day 21 to 28) and baseline values from 3 visits.
Safety Issue?	No

Analysis Population Description

The efficacy analysis set for each outcome measure includes those patients who received at least one dose of investigational product and for whom a baseline and at least one post-randomisation measurement is available for that outcome measure. Patients were analysed by to randomised treatment in accordance with the intention to treat principle.

Reporting Groups

	Description
AZD9668	AZD9668, 2 x 30 mg twice daily (bid)
Placebo	Placebo, 2 tablets twice daily (bid)

Measured Values

	AZD9668	Placebo
Number of Participants Analyzed	20	12

	AZD9668	Placebo
Ratio of Regulated on Activation, Normal T Cell Expressed and Secreted (RANTES) at End of Treatment Compared to Baseline [units: ratio] Least Squares Mean (95% Confidence Interval)	0.73 (0.60 to 0.88)	1.15 (0.90 to 1.48)

16. Secondary Outcome Measure:

Measure Title	Ratio of Monocyte Chemoattractant Protein-1 (MCP-1) at End of Treatment Compared to Baseline
Measure Description	Ratio of the mean of 3 visits at the end of the treatment period to the mean of the 3 baseline visits
Time Frame	End of treatment values from 3 visits (day 21 to 28) and baseline values from 3 visits.
Safety Issue?	No

Analysis Population Description

The efficacy analysis set for each outcome measure includes those patients who received at least one dose of investigational product and for whom a baseline and at least one post-randomisation measurement is available for that outcome measure. Patients were analysed by to randomised treatment in accordance with the intention to treat principle.

Reporting Groups

	Description
AZD9668	AZD9668, 2 x 30 mg twice daily (bid)
Placebo	Placebo, 2 tablets twice daily (bid)

Measured Values

	AZD9668	Placebo
Number of Participants Analyzed	20	12
Ratio of Monocyte Chemoattractant Protein-1 (MCP-1) at End of Treatment Compared to Baseline [units: ratio] Least Squares Mean (95% Confidence Interval)	0.79 (0.62 to 1.01)	1.07 (0.78 to 1.47)

17. Secondary Outcome Measure:

Measure Title	Ratio of Interleukin 8 (IL-8) at End of Treatment Compared to Baseline

Measure Description	Ratio of the mean of 3 visits at the end of the treatment period to the mean of the 3 baseline visits
Time Frame	End of treatment values from 3 visits (day 21 to 28) and baseline values from 3 visits.
Safety Issue?	No

Analysis Population Description

The efficacy analysis set for each outcome measure includes those patients who received at least one dose of investigational product and for whom a baseline and at least one post-randomisation measurement is available for that outcome measure. Patients were analysed by to randomised treatment in accordance with the intention to treat principle.

Reporting Groups

	Description
AZD9668	AZD9668, 2 x 30 mg twice daily (bid)
Placebo	Placebo, 2 tablets twice daily (bid)

Measured Values

	AZD9668	Placebo
Number of Participants Analyzed	20	12
Ratio of Interleukin 8 (IL-8) at End of Treatment Compared to Baseline [units: ratio] Least Squares Mean (95% Confidence Interval)	0.91 (0.67 to 1.23)	1.06 (0.71 to 1.58)

18. Secondary Outcome Measure:

Measure Title	Ratio of Leukotriene B4 (LTB4) at End of Treatment Compared to Baseline
Measure Description	Ratio of the mean of 3 visits at the end of the treatment period to the mean of the 3 baseline visits
Time Frame	End of treatment values from 3 visits (day 21 to 28) and baseline values from 3 visits.
Safety Issue?	No

Analysis Population Description

The efficacy analysis set for each outcome measure includes those patients who received at least one dose of investigational product and for whom a baseline and at least one post-randomisation measurement is available for that outcome measure. Patients were analysed by to randomised treatment in accordance with the intention to treat principle.

Reporting Groups

	Description
AZD9668	AZD9668, 2 x 30 mg twice daily (bid)
Placebo	Placebo, 2 tablets twice daily (bid)

Measured Values

	AZD9668	Placebo
Number of Participants Analyzed	20	12
Ratio of Leukotriene B4 (LTB4) at End of Treatment Compared to Baseline [units: ratio] Least Squares Mean (95% Confidence Interval)	0.83 (0.64 to 1.09)	0.91 (0.64 to 1.30)

19. Secondary Outcome Measure:

Measure Title	Ratio of Urine Desmosine (Free) (Normalised for Creatinine) at End of Treatment Compared to Baseline
Measure Description	Ratio of day 28 to baseline
Time Frame	Baseline and day 28
Safety Issue?	No

Analysis Population Description

The efficacy analysis set for each outcome measure includes those patients who received at least one dose of investigational product and for whom a baseline and at least one post-randomisation measurement is available for that outcome measure. Patients were analysed by to randomised treatment in accordance with the intention to treat principle.

Reporting Groups

	Description
AZD9668	AZD9668, 2 x 30 mg twice daily (bid)
Placebo	Placebo, 2 tablets twice daily (bid)

Measured Values

	AZD9668	Placebo
Number of Participants Analyzed	20	12

	AZD9668	Placebo
Ratio of Urine Desmosine (Free) (Normalised for Creatinine) at End of Treatment Compared to Baseline [units: ratio] Least Squares Mean (95% Confidence Interval)	0.98 (0.92 to 1.05)	0.96 (0.88 to 1.05)

20. Secondary Outcome Measure:

Measure Title	Ratio of Urine Desmosine (Total) (Normalised for Creatinine) at End of Treatment Compared to Baseline
Measure Description	Ratio of day 28 to baseline
Time Frame	Baseline and day 28
Safety Issue?	No

Analysis Population Description

The efficacy analysis set for each outcome measure includes those patients who received at least one dose of investigational product and for whom a baseline and at least one post-randomisation measurement is available for that outcome measure. Patients were analysed by to randomised treatment in accordance with the intention to treat principle.

Reporting Groups

	Description
AZD9668	AZD9668, 2 x 30 mg twice daily (bid)
Placebo	Placebo, 2 tablets twice daily (bid)

Measured Values

	AZD9668	Placebo
Number of Participants Analyzed	20	12
Ratio of Urine Desmosine (Total) (Normalised for Creatinine) at End of Treatment Compared to Baseline [units: ratio] Least Squares Mean (95% Confidence Interval)	0.96 (0.83 to 1.11)	1.05 (0.87 to 1.26)

Reported Adverse Events

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

Reporting Groups

	Description
AZD9668	AZD9668, 2 x 30 mg twice daily (bid)
Placebo	Placebo, 2 tablets twice daily (bid)

Serious Adverse Events

	AZD9668	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)
Total	0/22 (0%)	0/16 (0%)

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	AZD9668	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)
Total	13/22 (59.09%)	15/16 (93.75%)
Cardiac disorders		
Palpitations [A] †	0/22 (0%)	1/16 (6.25%)
Gastrointestinal disorders		
Abdominal Distension [A] †	0/22 (0%)	1/16 (6.25%)
Abdominal Pain [A] †	0/22 (0%)	1/16 (6.25%)
Abdominal Pain Upper [A] †	1/22 (4.55%)	1/16 (6.25%)
Constipation [A] †	0/22 (0%)	2/16 (12.5%)
Diarrhoea [A] †	2/22 (9.09%)	4/16 (25%)
Nausea [A] †	1/22 (4.55%)	1/16 (6.25%)

	AZD9668	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)
Vomiting [A] †	1/22 (4.55%)	1/16 (6.25%)
General disorders		
Chest Discomfort [A] †	0/22 (0%)	1/16 (6.25%)
Fatigue [A] †	0/22 (0%)	1/16 (6.25%)
Local Swelling [A] †	0/22 (0%)	1/16 (6.25%)
Oedema Peripheral [A] †	1/22 (4.55%)	2/16 (12.5%)
Infections and infestations		
Influenza [A] †	0/22 (0%)	1/16 (6.25%)
Nasopharyngitis [A] †	4/22 (18.18%)	0/16 (0%)
Sinusitis [A] †	0/22 (0%)	1/16 (6.25%)
Injury, poisoning and procedural complications		
Contusion [A] †	2/22 (9.09%)	1/16 (6.25%)
Fall [A] †	0/22 (0%)	1/16 (6.25%)
Thermal Burn [A] †	0/22 (0%)	1/16 (6.25%)
Metabolism and nutrition disorders		
Increased Appetite [A] †	0/22 (0%)	1/16 (6.25%)
Musculoskeletal and connective tissue disorders		
Arthralgia [A] †	2/22 (9.09%)	0/16 (0%)
Back Pain [A] †	1/22 (4.55%)	1/16 (6.25%)
Muscle Spasms [A] †	0/22 (0%)	1/16 (6.25%)
Musculoskeletal Chest Pain [A] †	2/22 (9.09%)	1/16 (6.25%)
Musculoskeletal Discomfort [A] †	0/22 (0%)	1/16 (6.25%)
Musculoskeletal Pain [A] †	0/22 (0%)	1/16 (6.25%)

	AZD9668	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)
Nervous system disorders		
Dizziness [A] †	0/22 (0%)	1/16 (6.25%)
Headache [A] †	7/22 (31.82%)	3/16 (18.75%)
Lethargy [A] †	1/22 (4.55%)	1/16 (6.25%)
Tremor [A] †	0/22 (0%)	1/16 (6.25%)
Psychiatric disorders		
Depressed Mood [A] †	0/22 (0%)	1/16 (6.25%)
Sleep Disorder [A] †	0/22 (0%)	1/16 (6.25%)
Reproductive system and breast disorders		
Erectile Dysfunction [A] †	0/22 (0%)	1/16 (6.25%)
Respiratory, thoracic and mediastinal disorders		
Cough [A] †	0/22 (0%)	1/16 (6.25%)
Dyspnoea [A] †	1/22 (4.55%)	1/16 (6.25%)
Haemoptysis [A] †	1/22 (4.55%)	1/16 (6.25%)
Oropharyngeal Pain [A] †	0/22 (0%)	2/16 (12.5%)
Rales [A] †	0/22 (0%)	1/16 (6.25%)
Skin and subcutaneous tissue disorders		
Alopecia [A] †	0/22 (0%)	1/16 (6.25%)
Vascular disorders		
Hyperaemia [A] †	0/22 (0%)	1/16 (6.25%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 12.0

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There is NOT 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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