

ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt Release Date: 12/17/2015

ClinicalTrials.gov ID: NCT00999466

Study Identification

Unique Protocol ID: D0540C00004

Brief Title: The Tolerability and Effects of AZD8848 in Allergic Asthma Subjects Challenged With Inhaled Allergen

Official Title: A Double-blind, Placebo-controlled, Randomised, Parallel Group, Phase IIa Study to Investigate the Efficacy, Tolerability and

Safety of 8 Doses of AZD8848 Administered Intranasally Once Weekly in Mild to Moderate Allergic Asthma Subjects Challenged

With an Inhaled Allergen.

Secondary IDs:

Study Status

Record Verification: December 2015

Overall Status: Completed

Study Start: October 2009

Primary Completion: February 2011 [Actual]

Study Completion: December 2011 [Actual]

Sponsor/Collaborators

Sponsor: AstraZeneca

Responsible Party: Sponsor

Collaborators:

Oversight

FDA Regulated?: No

IND/IDE Protocol?: No

Review Board: Approval Status: Approved

Approval Number: Reference 09/H0803/104

Board Name: Wandsworth Research Ethics Committee Board Affiliation: National Research Ethics Service (NRES)

Phone: 0044 (0) 20 8725 1558 Email: recwand@stgeorges.nhs.uk

Data Monitoring?: No

Plan to Share Data?:

Oversight Authorities: United Kingdom: Medicines and Healthcare Products Regulatory Agency

United Kingdom: Research Ethics Committee

Study Description

Brief Summary: AZD8848 is a new drug that is being tested for the treatment of asthma and allergic rhinitis (hayfever). This study will be in two

parts and will include 59 asthmatic patients in total. The first part will investigate the tolerability and safety of AZD8848 while the

second part will investigate both the therapeutic effect of AZD8848 and how well patients tolerate the drug.

Detailed Description:

Conditions

Conditions: Allergic Asthma

Keywords:

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 2

Intervention Model: Parallel Assignment

Number of Arms: 2

Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)

Allocation: Randomized

Endpoint Classification: Safety/Efficacy Study

Enrollment: 60 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: 1	Drug: AZD8848
AZD8848 (30 μg PILOT part and 60 μg MAIN part)	Nasal spray, solution 0.6mg/ mL. Once weekly for 7 weeks, 8 doses in total.
Placebo Comparator: 2	Drug: Placebo
Placebo	Nasal spray, solution. Once weekly for 7 weeks, 8 doses in total.

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years

Maximum Age: 55 Years

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- FEV1 > 70 % of predicted normal pre-bronchodilator
- · Documented history of asthma
- · Presence of allergic sensitivity

Exclusion Criteria:

- Clinically relevant disease and/or abnormality (past or present), which, in the opinion of the Investigator, may either put the patient at risk because of participation in the study, or influence the results of the study, or the patient's ability to participate in the study.
- · Symptomatic allergic rhinitis
- Any clinical relevant abnormal findings in physical examination or assessment which may put the patient at risk because of participation in the study

Contacts/Locations

Study Officials: Leif Eriksson, MD

Study Director

AstraZeneca R&D Lund

Brian Leaker, MD

Study Principal Investigator Respiratory Clinical Trials

Locations: United Kingdom

Research Site

London, United Kingdom

Research Site

Manchester, United Kingdom

References

Citations:

Links: URL: http://filehosting.pharmacm.com/DownloadService.ashx?client=CTR_MED_7111&studyid=191&fil...

Description CSR Synopsis

Study Data/Documents:

Study Results

Participant Flow

Reporting Groups

	Description	
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.	
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.	
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.	

Pilot Part

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Started	6	o ^[1]	3
Completed	6	0	3

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Not Completed	0	0	0

^[1] AZD8848 nasal spray 60 µg group was not participated in the Pilot part

Main Part

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Started	0 ^[1]	26	25
Completed	0	22	21
Not Completed	0	4	4
Withdrawal by Subject	0	0	2
Adverse Event	0	4	2

^[1] AZD8848 nasal spray 30 µg group was not participated in the Main part

Baseline Characteristics

Analysis Population Description

AZD8848 30 µg nasal spray was only done in Pilot part. 3 of the 28 placebo subjects were from the PILOT part and 25 placebo subjects were from the MAIN part.

Reporting Groups

	Description
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.

Baseline Measures

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo	Total
Number of Participants	6	26	28	60
Age, Continuous [units: Years] Mean (Full Range)	36.3 (23 to 47)	33.0 (19 to 51)	32.3 (21 to 50)	33.9 (19 to 51)

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo	Total
Gender, Male/Female [units: Participants]				
Female	0	7	7	14
Male	6	19	21	46

Outcome Measures

1. Primary Outcome Measure:

Measure Title	FEV1, Late Asthmatic Response (LAR) - Pre-treatment
Measure Description	Forced Expiratory Volume in 1 second (FEV1), Late Asthmatic Response (LAR), is derived as the ratio of FEV1 Area Under Curve 4-10 hour post allergen challenge (AUC 4-10h) (computed using the trapezoidal formula divided by time) and the pre-challenge FEV1 measurement.
Time Frame	Pre-treatment (Baseline measurement)
Safety Issue?	No

Analysis Population Description

AZD8848 30 µg nasal spray was only done in Pilot part. No efficacy comparisons were done for this group.

Reporting Groups

	Description	
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.	
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.	
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.	

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	22	23
FEV1, Late Asthmatic Response (LAR) - Pre- treatment [units: ratio] Mean (Standard Deviation)		0.814 (0.450)	1.01 (0.784)

2. Primary Outcome Measure:

Measure Title	FEV1, Late Asthmatic Response (LAR) - 1 Week After Last Dose
Measure Description	FEV1, Late Asthmatic Response (LAR), is derived as the ratio of FEV1 AUC 4-10h (computed using the trapezoidal formula divided by time) and the pre-challenge FEV1 measurement.
Time Frame	1 week after last dose
Safety Issue?	No

Analysis Population Description

AZD8848 30 μg nasal spray was only done in Pilot part. No efficacy comparisons were done for this group.

Reporting Groups

	Description	
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.	
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.	
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.	

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	22	23
FEV1, Late Asthmatic Response (LAR) - 1 Week After Last Dose [units: ratio] Mean (Standard Deviation)		0.616 (0.296)	0.970 (0.641)

3. Primary Outcome Measure:

Measure Title	FEV1, Late Asthmatic Response (LAR) - 4 Weeks After Last Dose
Measure Description	FEV1, Late Asthmatic Response (LAR), is derived as the ratio of FEV1 AUC 4-10h (computed using the trapezoidal formula divided by time) and the pre-challenge FEV1 measurement.
Time Frame	4 weeks after last dose
Safety Issue?	No

Analysis Population Description

AZD8848 30 µg nasal spray was only done in Pilot part. No efficacy comparisons were done for this group.

Reporting Groups

	Description	
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.	
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.	
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.	

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	22	21
FEV1, Late Asthmatic Response (LAR) - 4 Weeks After Last Dose [units: ratio] Mean (Standard Deviation)		0.759 (0.397)	0.722 (0.584)

4. Secondary Outcome Measure:

Measure Title	FEV1, Early Asthmatic Response (EAR) - Pre-treatment
Measure Description	FEV1, Early Asthmatic Response (EAR), is derived as the ratio of FEV1 Area Under Curve 0-2 hour post allergen challenge (AUC 0-2h) (computed using the trapezoidal formula divided by time) and the pre-challenge FEV1 measurement.
Time Frame	Pre-treatment (Baseline measurement)
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description	
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.	
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.	
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.	

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	22	23
FEV1, Early Asthmatic Response (EAR) - Pre- treatment [units: ratio] Mean (Standard Deviation)		0.524 (0.241)	0.611 (0.362)

5. Secondary Outcome Measure:

Measure Title	FEV1, Early Asthmatic Response (EAR) - 1 Week After Last Dose
Measure Description	FEV1, Early Asthmatic Response (EAR), is derived as the ratio of FEV1 AUC 0-2h (computed using the trapezoidal formula divided by time) and the pre-challenge FEV1 measurement.
Time Frame	1 week after last dose
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description	
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.	
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.	
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.	

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	22	23
FEV1, Early Asthmatic Response (EAR) - 1 Week After Last Dose [units: ratio] Mean (Standard Deviation)		0.468 (0.361)	0.624 (0.362)

Measure Title	FEV1, Early Asthmatic Response (EAR) - 4 Weeks After Last Dose
Measure Description	FEV1, Early Asthmatic Response (EAR), is derived as the ratio of FEV1 AUC 0-2h (computed using the trapezoidal formula divided by time) and the pre-challenge FEV1 measurement.
Time Frame	4 weeks after last dose
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description	
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.	
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.	
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.	

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	22	21
FEV1, Early Asthmatic Response (EAR) - 4 Weeks After Last Dose [units: ratio] Mean (Standard Deviation)		0.510 (0.240)	0.591 (0.401)

7. Secondary Outcome Measure:

Measure Title	PC20 Methacholine Challenge - Pre-treatment, Pre Allergen Challenge
Measure Description	PC20 is the provocation concentration of Methacholine causing a 20% fall in FEV1
Time Frame	Pre-treatment, pre allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description	
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.	
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.	
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.	

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	22	23
PC20 Methacholine Challenge - Pre-treatment, Pre Allergen Challenge [units: mg/mL] Geometric Mean (Full Range)		0.564 (0.004 to 11.1)	0.609 (0.063 to 5.69)

8. Secondary Outcome Measure:

Measure Title	PC20 Methacholine Challenge - Pre-treatment, Post Allergen Challenge	
Measure Description	PC20 is the provocation concentration of Methacholine causing a 20% fall in FEV1	
Time Frame	Pre-treatment, post allergen challenge	
Safety Issue?	No	

Analysis Population Description [Not Specified]

Reporting Groups

	Description	
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.	
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.	
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.	

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	22	23

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
PC20 Methacholine Challenge - Pre-treatment, Post Allergen Challenge [units: mg/mL] Geometric Mean (Full Range)		0.425 (0.123 to 6.25)	0.364 (0.063 to 10.2)

Measure Title	PC20 Methacholine Challenge - 1 Week After Last Dose, Pre Allergen Challenge
Measure Description	PC20 is the provocation concentration of Methacholine causing a 20% fall in FEV1
Time Frame	1 week after last dose, pre allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description	
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.	
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.	
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.	

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	22	21
PC20 Methacholine Challenge - 1 Week After Last Dose, Pre Allergen Challenge [units: mg/mL] Geometric Mean (Full Range)		0.488 (0.063 to 3.01)	0.454 (0.063 to 8.25)

10. Secondary Outcome Measure:

Measure Title	PC20 Methacholine Challenge - 1 Week After Last Dose, Post Allergen Challenge
Measure Description	PC20 is the provocation concentration of Methacholine causing a 20% fall in FEV1

Time Frame	1 week after last dose, post allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description	
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.	
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.	
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.	

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	21	21
PC20 Methacholine Challenge - 1 Week After Last Dose, Post Allergen Challenge [units: mg/mL] Geometric Mean (Full Range)		0.691 (0.063 to 9.13)	0.340 (0.063 to 17.8)

11. Secondary Outcome Measure:

Measure Title	PC20 Methacholine Challenge - 4 Weeks After Last Dose, Pre Allergen Challenge	
Measure Description	PC20 is the provocation concentration of Methacholine causing a 20% fall in FEV1	
Time Frame	4 weeks after last dose, pre allergen challenge	
Safety Issue?	No	

Analysis Population Description [Not Specified]

Reporting Groups

	Description
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.

	Description
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	22	21
PC20 Methacholine Challenge - 4 Weeks After Last Dose, Pre Allergen Challenge [units: mg/mL] Geometric Mean (Full Range)		0.468 (0.063 to 2.47)	0.504 (0.072 to 4.00)

12. Secondary Outcome Measure:

Measure Title	PC20 Methacholine Challenge - 4 Weeks After Last Dose, Post Allergen Challenge	
Measure Description	PC20 is the provocation concentration of Methacholine causing a 20% fall in FEV1	
Time Frame	4 weeks after last dose, post allergen challenge	
Safety Issue?	No	

Analysis Population Description [Not Specified]

Reporting Groups

	Description
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	21	20
PC20 Methacholine Challenge - 4 Weeks After Last Dose, Post Allergen Challenge [units: mg/mL] Geometric Mean (Full Range)		0.326 (0.082 to 4.08)	0.508 (0.063 to 29.1)

Measure Title	Sputum Cellularity and Cytokines, Tumour Necrosis Factor Alpha (TNFα) - Pre-treatment, Pre Allergen Challenge
Measure Description	
Time Frame	Pre-treatment, pre allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description	
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.	
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.	
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.	

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	12	19
Sputum Cellularity and Cytokines, Tumour Necrosis Factor Alpha (TNFα) - Pre-treatment, Pre Allergen Challenge [units: pg/mL] Geometric Mean (Full Range)		8.9 (3.5 to 25)	4.8 (0.90 to 24)

14. Secondary Outcome Measure:

Measure Title	Sputum Cellularity and Cytokines, TNFα - Pre-treatment, Post Allergen Challenge
Measure Description	
Time Frame	Pre-treatment, post allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description	
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.	
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.	
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.	

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	17	17
Sputum Cellularity and Cytokines, TNFα - Pre- treatment, Post Allergen Challenge [units: pg/mL] Geometric Mean (Full Range)		13 (2.8 to 156)	12 (5.3 to 38)

15. Secondary Outcome Measure:

Measure Title	Sputum Cellularity and Cytokines, TNFα - 1 Week After Last Dose, Pre Allergen Challenge
Measure Description	
Time Frame	1 week after last dose, pre allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description	
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.	
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.	
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.	

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	16	19
Sputum Cellularity and Cytokines, TNFα - 1 Week After Last Dose, Pre Allergen Challenge [units: pg/mL] Geometric Mean (Full Range)		6.5 (1.7 to 46)	5.3 (0.90 to 23)

16. Secondary Outcome Measure:

Measure Title	Sputum Cellularity and Cytokines, TNFα - 1 Week After Last Dose, Post Allergen Challenge
Measure Description	
Time Frame	1 week after last dose, post allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	17	17
Sputum Cellularity and Cytokines, TNFα - 1 Week After Last Dose, Post Allergen Challenge [units: pg/mL] Geometric Mean (Full Range)		11 (2.4 to 539)	8.4 (1.1 to 41)

Measure Title	Sputum Cellularity and Cytokines, TNFα - 4 Weeks After Last Dose, Pre Allergen Challenge
Measure Description	
Time Frame	4 weeks after last dose, pre allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description	
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.	
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.	
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.	

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	16	17
Sputum Cellularity and Cytokines, TNFα - 4 Weeks After Last Dose, Pre Allergen Challenge [units: pg/mL] Geometric Mean (Full Range)		5.1 (0.90 to 113)	9.4 (1.5 to 510)

18. Secondary Outcome Measure:

Measure Title	Sputum Cellularity and Cytokines, TNFα - 4 Weeks After Last Dose, Post Allergen Challenge
Measure Description	
Time Frame	4 weeks after last dose, post allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description	
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.	
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.	
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.	

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	13	16
Sputum Cellularity and Cytokines, TNFα - 4 Weeks After Last Dose, Post Allergen Challenge [units: pg/mL] Geometric Mean (Full Range)		13 (4.3 to 125)	7.9 (4.4 to 23)

19. Secondary Outcome Measure:

Measure Title	Sputum Cellularity and Cytokines, Interleukin-1β (IL-1β) - Pre-treatment, Pre Allergen Challenge
Measure Description	
Time Frame	Pre-treatment, pre allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description	
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.	
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.	
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.	

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	12	19

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Sputum Cellularity and Cytokines, Interleukin-1β (IL-1β) - Pre-treatment, Pre Allergen Challenge [units: pg/mL] Geometric Mean (Full Range)		37 (6.5 to 127)	23 (0.80 to 243)

Measure Title	Sputum Cellularity and Cytokines, IL-1β - Pre-treatment, Post Allergen Challenge
Measure Description	
Time Frame	Pre-treatment, post allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description	
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.	
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.	
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.	

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	17	17
Sputum Cellularity and Cytokines, IL-1β - Pretreatment, Post Allergen Challenge [units: pg/mL] Geometric Mean (Full Range)		41 (13 to 322)	44 (13 to 320)

21. Secondary Outcome Measure:

Measure Title	Sputum Cellularity and Cytokines, IL-1β - 1 Week After Last Dose, Pre Allergen Challenge
Measure Description	

Time Frame	1 week after last dose, pre allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	16	19
Sputum Cellularity and Cytokines, IL-1β - 1 Week After Last Dose, Pre Allergen Challenge [units: pg/mL] Geometric Mean (Full Range)		37 (7.8 to 614)	36 (4.5 to 139)

22. Secondary Outcome Measure:

Measure Title	Sputum Cellularity and Cytokines, IL-1β - 1 Week After Last Dose, Post Allergen Challenge
Measure Description	
Time Frame	1 week after last dose, post allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.

	Description
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	17	17
Sputum Cellularity and Cytokines, IL-1β - 1 Week After Last Dose, Post Allergen Challenge [units: pg/mL] Geometric Mean (Full Range)		45 (7.0 to 293)	37 (13 to 217)

23. Secondary Outcome Measure:

Measure Title	Sputum Cellularity and Cytokines, IL-1β - 4 Weeks After Last Dose, Pre Allergen Challenge
Measure Description	
Time Frame	4 weeks after last dose, pre allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	16	17
Sputum Cellularity and Cytokines, IL-1β - 4 Weeks After Last Dose, Pre Allergen Challenge [units: pg/mL] Geometric Mean (Full Range)		29 (6.6 to 303)	43 (7.6 to 366)

Measure Title	Sputum Cellularity and Cytokines, IL-1β - 4 Weeks After Last Dose, Post Allergen Challenge
Measure Description	
Time Frame	4 weeks after last dose, post allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description	
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.	
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.	
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.	

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	13	16
Sputum Cellularity and Cytokines, IL-1β - 4 Weeks After Last Dose, Post Allergen Challenge [units: pg/mL] Geometric Mean (Full Range)		72 (15 to 198)	41 (15 to 224)

25. Secondary Outcome Measure:

Measure Title	Sputum Cellularity and Cytokines, Interleukin-5 (IL-5) - Pre-treatment, Pre Allergen Challenge
Measure Description	
Time Frame	Pre-treatment, pre allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description	
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.	
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.	
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.	

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	12	19
Sputum Cellularity and Cytokines, Interleukin-5 (IL-5) - Pre-treatment, Pre Allergen Challenge [units: pg/mL] Geometric Mean (Full Range)		0.83 (0.40 to 9.0)	0.87 (0.40 to 5.6)

26. Secondary Outcome Measure:

Measure Title	Sputum Cellularity and Cytokines, IL-5 - Pre-treatment, Post Allergen Challenge
Measure Description	
Time Frame	Pre-treatment, post allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description	
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.	
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.	
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.	

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	17	17

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Sputum Cellularity and Cytokines, IL-5 - Pretreatment, Post Allergen Challenge [units: pg/mL] Geometric Mean (Full Range)		7.1 (0.40 to 74)	5.8 (0.40 to 27)

Measure Title	Sputum Cellularity and Cytokines, IL-5 - 1 Week After Last Dose, Pre Allergen Challenge
Measure Description	
Time Frame	1 week after last dose, pre allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description	
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.	
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.	
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.	

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	16	19
Sputum Cellularity and Cytokines, IL-5 - 1 Week After Last Dose, Pre Allergen Challenge [units: pg/mL] Geometric Mean (Full Range)		0.82 (0.40 to 4.5)	1.3 (0.40 to 11)

28. Secondary Outcome Measure:

Measure Title	Sputum Cellularity and Cytokines, IL-5 - 1 Week After Last Dose, Post Allergen Challenge
Measure Description	

Time Frame	1 week after last dose, post allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description	
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.	
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.	
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.	

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	17	17
Sputum Cellularity and Cytokines, IL-5 - 1 Week After Last Dose, Post Allergen Challenge [units: pg/mL] Geometric Mean (Full Range)		7.8 (1.1 to 38)	5.4 (0.90 to 35)

29. Secondary Outcome Measure:

Measure Title	Sputum Cellularity and Cytokines, IL-5 - 4 Weeks After Last Dose, Pre Allergen Challenge
Measure Description	
Time Frame	4 weeks after last dose, pre allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.

	Description
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	16	17
Sputum Cellularity and Cytokines, IL-5 - 4 Weeks After Last Dose, Pre Allergen Challenge [units: pg/mL] Geometric Mean (Full Range)		1.2 (0.40 to 5.5)	1.7 (0.40 to 24)

30. Secondary Outcome Measure:

Measure Title	Sputum Cellularity and Cytokines, IL-5 - 4 Weeks After Last Dose, Post Allergen Challenge
Measure Description	
Time Frame	4 weeks after last dose, post allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description	
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.	
AZD8848, 60 μg	ZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.	
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.	

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	13	16
Sputum Cellularity and Cytokines, IL-5 - 4 Weeks After Last Dose, Post Allergen Challenge [units: pg/mL] Geometric Mean (Full Range)		5.7 (0.80 to 38)	8.0 (2.1 to 47)

Measure Title	Sputum Cellularity and Cytokines, Interleukin-6 (IL-6) - Pre-treatment, Pre Allergen Challenge
Measure Description	
Time Frame	Pre-treatment, pre allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description	
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.	
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.	
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.	

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	12	19
Sputum Cellularity and Cytokines, Interleukin-6 (IL-6) - Pre-treatment, Pre Allergen Challenge [units: pg/mL] Geometric Mean (Full Range)		15 (4.4 to 61)	9.4 (0.40 to 189)

32. Secondary Outcome Measure:

Measure Title	Sputum Cellularity and Cytokines, IL-6 - Pre-treatment, Post Allergen Challenge
Measure Description	
Time Frame	Pre-treatment, post allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description	
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.	
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.	
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.	

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	17	17
Sputum Cellularity and Cytokines, IL-6 - Pretreatment, Post Allergen Challenge [units: pg/mL] Geometric Mean (Full Range)		28 (5.7 to 252)	27 (1.7 to 75)

33. Secondary Outcome Measure:

Measure Title	Sputum Cellularity and Cytokines, IL-6 - 1 Week After Last Dose, Pre Allergen Challenge
Measure Description	
Time Frame	1 week after last dose, pre allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description	
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.	
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.	
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.	

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	16	19

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Sputum Cellularity and Cytokines, IL-6 - 1 Week After Last Dose, Pre Allergen Challenge [units: pg/mL] Geometric Mean (Full Range)		15 (2.4 to 43)	9.6 (0.40 to 37)

Measure Title	Sputum Cellularity and Cytokines, IL-6 - 1 Week After Last Dose, Post Allergen Challenge
Measure Description	
Time Frame	1 week after last dose, post allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description	
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.	
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.	
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.	

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	17	17
Sputum Cellularity and Cytokines, IL-6 - 1 Week After Last Dose, Post Allergen Challenge [units: pg/mL] Geometric Mean (Full Range)		26 (5.2 to 142)	23 (3.1 to 76)

35. Secondary Outcome Measure:

Measure Title	Sputum Cellularity and Cytokines, IL-6 - 4 Weeks After Last Dose, Pre Allergen Challenge
Measure Description	

Time Frame	4 weeks after last dose, pre allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description	
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.	
AZD8848, 60 μg	ZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.	
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.	

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	16	17
Sputum Cellularity and Cytokines, IL-6 - 4 Weeks After Last Dose, Pre Allergen Challenge [units: pg/mL] Geometric Mean (Full Range)		12 (0.60 to 123)	21 (6.3 to 1317)

36. Secondary Outcome Measure:

Measure Title	Sputum Cellularity and Cytokines, IL-6 - 4 Weeks After Last Dose, Post Allergen Challenge
Measure Description	
Time Frame	4 weeks after last dose, post allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.

	Description
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	13	16
Sputum Cellularity and Cytokines, IL-6 - 4 Weeks After Last Dose, Post Allergen Challenge [units: pg/mL] Geometric Mean (Full Range)		20 (5.3 to 174)	29 (10 to 107)

37. Secondary Outcome Measure:

Measure Title	Sputum Cellularity and Cytokines, Interleukin-8 (IL-8) - Pre-treatment, Pre Allergen Challenge	
Measure Description		
Time Frame	Pre-treatment, pre allergen challenge	
Safety Issue?	No	

Analysis Population Description [Not Specified]

Reporting Groups

	Description
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	12	19
Sputum Cellularity and Cytokines, Interleukin-8 (IL-8) - Pre-treatment, Pre Allergen Challenge [units: pg/mL] Geometric Mean (Full Range)		766 (138 to 1784)	522 (8.5 to 2500)

Measure Title	Sputum Cellularity and Cytokines, IL-8 - Pre-treatment, Post Allergen Challenge
Measure Description	
Time Frame	Pre-treatment, post allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description	
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.	
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.	
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.	

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	17	17
Sputum Cellularity and Cytokines, IL-8 - Pretreatment, Post Allergen Challenge [units: pg/mL] Geometric Mean (Full Range)		1300 (422 to 2500)	1450 (549 to 2500)

39. Secondary Outcome Measure:

Measure Title	Sputum Cellularity and Cytokines, IL-8 - 1 Week After Last Dose, Pre Allergen Challenge
Measure Description	
Time Frame	1 week after last dose, pre allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description	
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.	
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.	
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.	

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	16	19
Sputum Cellularity and Cytokines, IL-8 - 1 Week After Last Dose, Pre Allergen Challenge [units: pg/mL] Geometric Mean (Full Range)		720 (186 to 2500)	609 (63 to 2366)

40. Secondary Outcome Measure:

Measure Title	Sputum Cellularity and Cytokines, IL-8 - 1 Week After Last Dose, Post Allergen Challenge
Measure Description	
Time Frame	1 week after last dose, post allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description	
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.	
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.	
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.	

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	17	17

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Sputum Cellularity and Cytokines, IL-8 - 1 Week After Last Dose, Post Allergen Challenge [units: pg/mL] Geometric Mean (Full Range)		1272 (284 to 2500)	1270 (240 to 2500)

Measure Title	Sputum Cellularity and Cytokines, IL-8 - 4 Weeks After Last Dose, Pre Allergen Challenge
Measure Description	
Time Frame	4 weeks after last dose, pre allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description	
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.	
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.	
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.	

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	16	17
Sputum Cellularity and Cytokines, IL-8 - 4 Weeks After Last Dose, Pre Allergen Challenge [units: pg/mL] Geometric Mean (Full Range)		496 (68 to 2500)	1012 (176 to 2500)

42. Secondary Outcome Measure:

Measure Title	Sputum Cellularity and Cytokines, IL-8 - 4 Weeks After Last Dose, Post Allergen Challenge
Measure Description	

Time Frame	4 weeks after last dose, post allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description	
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.	
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.	
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.	

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	13	16
Sputum Cellularity and Cytokines, IL-8 - 4 Weeks After Last Dose, Post Allergen Challenge [units: pg/mL] Geometric Mean (Full Range)		1500 (783 to 2500)	1304 (595 to 2500)

43. Secondary Outcome Measure:

Measure Title	Sputum Cellularity and Cytokines, Interleukin-10 (IL-10) - Pre-treatment, Pre Allergen Challenge
Measure Description	
Time Frame	Pre-treatment, pre allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description	
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.	
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.	

	Description
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	12	19
Sputum Cellularity and Cytokines, Interleukin-10 (IL-10) - Pre-treatment, Pre Allergen Challenge [units: pg/mL] Geometric Mean (Full Range)		0.57 (0.50 to 1.1)	0.63 (0.50 to 2.6)

44. Secondary Outcome Measure:

Measure Title	Sputum Cellularity and Cytokines, IL-10 - Pre-treatment, Post Allergen Challenge
Measure Description	
Time Frame	Pre-treatment, post allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description	
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.	
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.	
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.	

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	17	17
Sputum Cellularity and Cytokines, IL-10 - Pre- treatment, Post Allergen Challenge [units: pg/mL] Geometric Mean (Full Range)		0.86 (0.50 to 32)	0.68 (0.50 to 1.7)

Measure Title	Sputum Cellularity and Cytokines, IL-10 - 1 Week After Last Dose, Pre Allergen Challenge
Measure Description	
Time Frame	1 week after last dose, pre allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description	
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.	
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.	
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.	

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	16	19
Sputum Cellularity and Cytokines, IL-10 - 1 Week After Last Dose, Pre Allergen Challenge [units: pg/mL] Geometric Mean (Full Range)		0.60 (0.50 to 2.5)	0.75 (0.50 to 34)

46. Secondary Outcome Measure:

Measure Title	Sputum Cellularity and Cytokines, IL-10 - 1 Week After Last Dose, Post Allergen Challenge
Measure Description	
Time Frame	1 week after last dose, post allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description	
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.	
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.	
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.	

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	17	17
Sputum Cellularity and Cytokines, IL-10 - 1 Week After Last Dose, Post Allergen Challenge [units: pg/mL] Geometric Mean (Full Range)		0.79 (0.50 to 53)	0.82 (0.50 to 3.0)

47. Secondary Outcome Measure:

Measure Title	Sputum Cellularity and Cytokines, IL-10 - 4 Weeks After Last Dose, Pre Allergen Challenge
Measure Description	
Time Frame	4 weeks after last dose, pre allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	16	17

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Sputum Cellularity and Cytokines, IL-10 - 4 Weeks After Last Dose, Pre Allergen Challenge [units: pg/mL] Geometric Mean (Full Range)		0.54 (0.50 to 0.90)	0.95 (0.50 to 17)

Measure Title	Sputum Cellularity and Cytokines, IL-10 - 4 Weeks After Last Dose, Post Allergen Challenge
Measure Description	
Time Frame	4 weeks after last dose, post allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	13	16
Sputum Cellularity and Cytokines, IL-10 - 4 Weeks After Last Dose, Post Allergen Challenge [units: pg/mL] Geometric Mean (Full Range)		0.68 (0.50 to 1.9)	0.67 (0.50 to 5.7)

49. Secondary Outcome Measure:

Measure Title	Sputum Cellularity and Cytokines, Interleukin-13 (IL-13) - Pre-treatment, Pre Allergen Challenge
Measure Description	

Time Frame	Pre-treatment, pre allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	12	19
Sputum Cellularity and Cytokines, Interleukin-13 (IL-13) - Pre-treatment, Pre Allergen Challenge [units: pg/mL] Geometric Mean (Full Range)		1.3 (1.2 to 3.6)	1.4 (1.2 to 3.8)

50. Secondary Outcome Measure:

Measure Title	Sputum Cellularity and Cytokines, IL-13 - Pre-treatment, Post Allergen Challenge
Measure Description	
Time Frame	Pre-treatment, post allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.

	Description
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	17	17
Sputum Cellularity and Cytokines, IL-13 - Pretreatment, Post Allergen Challenge [units: pg/mL] Geometric Mean (Full Range)		3.0 (1.2 to 25)	3.1 (1.2 to 9.2)

51. Secondary Outcome Measure:

Measure Title	Sputum Cellularity and Cytokines, IL-13 - 1 Week After Last Dose, Pre Allergen Challenge
Measure Description	
Time Frame	1 week after last dose, pre allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description	
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.	
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.	
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.	

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	16	19
Sputum Cellularity and Cytokines, IL-13 - 1 Week After Last Dose, Pre Allergen Challenge [units: pg/mL] Geometric Mean (Full Range)		1.3 (1.2 to 1.9)	1.8 (1.2 to 8.0)

Measure Title	Sputum Cellularity and Cytokines, IL-13 - 1 Week After Last Dose, Post Allergen Challenge
Measure Description	
Time Frame	1 week after last dose, post allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description	
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.	
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.	
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.	

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	17	17
Sputum Cellularity and Cytokines, IL-13 - 1 Week After Last Dose, Post Allergen Challenge [units: pg/mL] Geometric Mean (Full Range)		3.0 (1.2 to 8.3)	2.8 (1.2 to 20)

53. Secondary Outcome Measure:

Measure Title	Sputum Cellularity and Cytokines, IL-13 - 4 Weeks After Last Dose, Pre Allergen Challenge
Measure Description	
Time Frame	4 weeks after last dose, pre allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description	
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.	
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.	
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.	

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	16	17
Sputum Cellularity and Cytokines, IL-13 - 4 Weeks After Last Dose, Pre Allergen Challenge [units: pg/mL] Geometric Mean (Full Range)		1.3 (1.2 to 2.1)	1.6 (1.2 to 6.5)

54. Secondary Outcome Measure:

Measure Title	Sputum Cellularity and Cytokines, IL-13 - 4 Weeks After Last Dose, Post Allergen Challenge
Measure Description	
Time Frame	4 weeks after last dose, post allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	13	16

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Sputum Cellularity and Cytokines, IL-13 - 4 Weeks After Last Dose, Post Allergen Challenge [units: pg/mL] Geometric Mean (Full Range)		2.5 (1.2 to 11)	3.1 (1.2 to 17)

Measure Title	Sputum Cellularity and Cytokines, Total Cells/g - Pre-treatment, Pre Allergen Challenge
Measure Description	
Time Frame	Pre-treatment, pre allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	12	19
Sputum Cellularity and Cytokines, Total Cells/g - Pretreatment, Pre Allergen Challenge [units: Cell count/g] Geometric Mean (Full Range)		2.7 (1.3 to 6.8)	2.7 (0.67 to 14)

56. Secondary Outcome Measure:

Measure Title	Sputum Cellularity and Cytokines, Total Cells/g - Pre-treatment, Post Allergen Challenge
Measure Description	

Time Frame	Pre-treatment, post allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	17	17
Sputum Cellularity and Cytokines, Total Cells/g - Pretreatment, Post Allergen Challenge [units: Cell count/g] Geometric Mean (Full Range)		5.0 (1.1 to 35)	3.5 (0.25 to 7.9)

57. Secondary Outcome Measure:

Measure Title	Sputum Cellularity and Cytokines, Total Cells/g - 1 Week After Last Dose, Pre Allergen Challenge
Measure Description	
Time Frame	1 week after last dose, pre allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.

	Description
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	16	19
Sputum Cellularity and Cytokines, Total Cells/g - 1 Week After Last Dose, Pre Allergen Challenge [units: Cell count/g] Geometric Mean (Full Range)		3.7 (0.84 to 16)	3.0 (0.95 to 20)

58. Secondary Outcome Measure:

Measure Title	Sputum Cellularity and Cytokines, Total Cells/g - 1 Week After Last Dose, Post Allergen Challenge
Measure Description	
Time Frame	1 week after last dose, post allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description	
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.	
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.	
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.	

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	17	17
Sputum Cellularity and Cytokines, Total Cells/g - 1 Week After Last Dose, Post Allergen Challenge [units: Cell count/g] Geometric Mean (Full Range)		5.0 (1.9 to 19)	4.2 (0.55 to 18)

Measure Title	Sputum Cellularity and Cytokines, Total Cells/g - 4 Weeks After Last Dose, Pre Allergen Challenge
Measure Description	
Time Frame	4 weeks after last dose, pre allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description	
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.	
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.	
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.	

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	16	16
Sputum Cellularity and Cytokines, Total Cells/g - 4 Weeks After Last Dose, Pre Allergen Challenge [units: Cell count/g] Geometric Mean (Full Range)		1.9 (0.29 to 9.4)	2.6 (0.58 to 12)

60. Secondary Outcome Measure:

Measure Title	Sputum Cellularity and Cytokines, Total Cells/g - 4 Weeks After Last Dose, Post Allergen Challenge
Measure Description	
Time Frame	4 weeks after last dose, post allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description	
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.	
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.	
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.	

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	13	16
Sputum Cellularity and Cytokines, Total Cells/g - 4 Weeks After Last Dose, Post Allergen Challenge [units: Cell count/g] Geometric Mean (Full Range)		5.2 (2.2 to 15)	4.0 (1.2 to 12)

61. Secondary Outcome Measure:

Measure Title	Sputum Cellularity and Cytokines, Eosinophils - Pre-treatment, Pre Allergen Challenge
Measure Description	
Time Frame	Pre-treatment, pre allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	12	19

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Sputum Cellularity and Cytokines, Eosinophils - Pretreatment, Pre Allergen Challenge [units: 10^6 cells/g] Geometric Mean (Full Range)		0.13 (0.015 to 0.46)	0.12 (0.008 to 3.7)

Measure Title	Sputum Cellularity and Cytokines, Eosinophils - Pre-treatment, Post Allergen Challenge
Measure Description	
Time Frame	Pre-treatment, post allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	17	17
Sputum Cellularity and Cytokines, Eosinophils - Pretreatment, Post Allergen Challenge [units: 10^6 cells/g] Geometric Mean (Full Range)		0.64 (0.008 to 6.5)	0.81 (0.023 to 3.0)

63. Secondary Outcome Measure:

Measure Title	Sputum Cellularity and Cytokines, Eosinophils - 1 Week After Last Dose, Pre Allergen Challenge
Measure Description	

Time Frame	1 week after last dose, pre allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	16	19
Sputum Cellularity and Cytokines, Eosinophils - 1 Week After Last Dose, Pre Allergen Challenge [units: 10^6 cells/g] Geometric Mean (Full Range)		0.18 (0.033 to 2.1)	0.23 (0.008 to 2.8)

64. Secondary Outcome Measure:

Measure Title	Sputum Cellularity and Cytokines, Eosinophils - 1 Week After Last Dose, Post Allergen Challenge
Measure Description	
Time Frame	1 week after last dose, post allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description	
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.	
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.	

	Description
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	17	17
Sputum Cellularity and Cytokines, Eosinophils - 1 Week After Last Dose, Post Allergen Challenge [units: 10^6 cells/g] Geometric Mean (Full Range)		0.94 (0.12 to 3.8)	0.82 (0.066 to 6.0)

65. Secondary Outcome Measure:

Measure Title	Sputum Cellularity and Cytokines, Eosinophils - 4 Weeks After Last Dose, Pre Allergen Challenge
Measure Description	
Time Frame	4 weeks after last dose, pre allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description	
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.	
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.	
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.	

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	16	16
Sputum Cellularity and Cytokines, Eosinophils - 4 Weeks After Last Dose, Pre Allergen Challenge [units: 10^6 cells/g] Geometric Mean (Full Range)		0.13 (0.009 to 2.2)	0.21 (0.032 to 1.1)

Measure Title	Sputum Cellularity and Cytokines, Eosinophils - 4 Weeks After Last Dose, Post Allergen Challenge
Measure Description	
Time Frame	4 weeks after last dose, post allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description	
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.	
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.	
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.	

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	13	16
Sputum Cellularity and Cytokines, Eosinophils - 4 Weeks After Last Dose, Post Allergen Challenge [units: 10^6 cells/g] Geometric Mean (Full Range)		1.0 (0.20 to 5.8)	0.96 (0.13 to 4.6)

67. Secondary Outcome Measure:

Measure Title	Sputum Cellularity and Cytokines, Neutrophils - Pre-treatment, Pre Allergen Challenge
Measure Description	
Time Frame	Pre-treatment, pre allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description	
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.	
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.	
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.	

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	12	19
Sputum Cellularity and Cytokines, Neutrophils - Pretreatment, Pre Allergen Challenge [units: 10^6 cells/g] Geometric Mean (Full Range)		0.75 (0.026 to 4.2)	0.93 (0.026 to 10)

68. Secondary Outcome Measure:

Measure Title	Sputum Cellularity and Cytokines, Neutrophils - Pre-treatment, Post Allergen Challenge
Measure Description	
Time Frame	Pre-treatment, post allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	17	17

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Sputum Cellularity and Cytokines, Neutrophils - Pretreatment, Post Allergen Challenge [units: 10^6 cells/g] Geometric Mean (Full Range)		1.9 (0.45 to 25)	1.5 (0.061 to 4.1)

Measure Title	Sputum Cellularity and Cytokines, Neutrophils - 1 Week After Last Dose, Pre Allergen Challenge
Measure Description	
Time Frame	1 week after last dose, pre allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	16	19
Sputum Cellularity and Cytokines, Neutrophils - 1 Week After Last Dose, Pre Allergen Challenge [units: 10^6 cells/g] Geometric Mean (Full Range)		1.5 (0.065 to 15)	0.91 (0.026 to 17)

70. Secondary Outcome Measure:

Measure Title	Sputum Cellularity and Cytokines, Neutrophils - 1 Week After Last Dose, Post Allergen Challenge
Measure Description	

Time Frame	1 week after last dose, post allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	17	17
Sputum Cellularity and Cytokines, Neutrophils - 1 Week After Last Dose, Post Allergen Challenge [units: 10^6 cells/g] Geometric Mean (Full Range)		2.1 (0.36 to 9.1)	1.7 (0.22 to 15)

71. Secondary Outcome Measure:

Measure Title	Sputum Cellularity and Cytokines, Neutrophils - 4 Weeks After Last Dose, Pre Allergen Challenge
Measure Description	
Time Frame	4 weeks after last dose, pre allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.

	Description
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	16	16
Sputum Cellularity and Cytokines, Neutrophils - 4 Weeks After Last Dose, Pre Allergen Challenge [units: 10^6 cells/g] Geometric Mean (Full Range)		0.80 (0.097 to 7.5)	1.3 (0.072 to 9.3)

72. Secondary Outcome Measure:

Measure Title	Sputum Cellularity and Cytokines, Neutrophils - 4 Weeks After Last Dose, Post Allergen Challenge
Measure Description	
Time Frame	4 weeks after last dose, post allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description	
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.	
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.	
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.	

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	13	16
Sputum Cellularity and Cytokines, Neutrophils - 4 Weeks After Last Dose, Post Allergen Challenge [units: 10^6 cells/g] Geometric Mean (Full Range)		2.6 (0.81 to 11)	1.6 (0.40 to 7.8)

Measure Title	Sputum Cellularity and Cytokines, Macrophages - Pre-treatment, Pre Allergen Challenge
Measure Description	
Time Frame	Pre-treatment, pre allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description	
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.	
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.	
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.	

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	12	19
Sputum Cellularity and Cytokines, Macrophages - Pre-treatment, Pre Allergen Challenge [units: 10^6 cells/g] Geometric Mean (Full Range)		1.1 (0.29 to 2.2)	0.59 (0.004 to 3.7)

74. Secondary Outcome Measure:

Measure Title	Sputum Cellularity and Cytokines, Macrophages - Pre-treatment, Post Allergen Challenge
Measure Description	
Time Frame	Pre-treatment, post allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description	
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.	
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.	
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.	

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	17	17
Sputum Cellularity and Cytokines, Macrophages - Pre-treatment, Post Allergen Challenge [units: 10^6 cells/g] Geometric Mean (Full Range)		1.1 (0.13 to 4.9)	0.60 (0.10 to 2.1)

75. Secondary Outcome Measure:

Measure Title	Sputum Cellularity and Cytokines, Macrophages - 1 Week After Last Dose, Pre Allergen Challenge
Measure Description	
Time Frame	1 week after last dose, pre allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	16	19

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Sputum Cellularity and Cytokines, Macrophages - 1 Week After Last Dose, Pre Allergen Challenge [units: 10^6 cells/g] Geometric Mean (Full Range)		0.80 (0.088 to 3.1)	0.36 (0.004 to 2.4)

Measure Title	Sputum Cellularity and Cytokines, Macrophages - 1 Week After Last Dose, Post Allergen Challenge
Measure Description	
Time Frame	1 week after last dose, post allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	17	17
Sputum Cellularity and Cytokines, Macrophages - 1 Week After Last Dose, Post Allergen Challenge [units: 10^6 cells/g] Geometric Mean (Full Range)		1.0 (0.20 to 5.2)	0.77 (0.12 to 3.0)

77. Secondary Outcome Measure:

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Measure Title	Sputum Cellularity and Cytokines, Macrophages - 4 Weeks After Last Dose, Pre Allergen Challenge
Measure Description	

Time Frame	4 weeks after last dose, pre allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	16	16
Sputum Cellularity and Cytokines, Macrophages - 4 Weeks After Last Dose, Pre Allergen Challenge [units: 10^6 cells/g] Geometric Mean (Full Range)		0.47 (0.004 to 1.9)	0.58 (0.22 to 1.6)

78. Secondary Outcome Measure:

Measure Title	Sputum Cellularity and Cytokines, Macrophages - 4 Weeks After Last Dose, Post Allergen Challenge
Measure Description	
Time Frame	4 weeks after last dose, post allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description	
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.	
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.	

	Description
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	13	16
Sputum Cellularity and Cytokines, Macrophages - 4 Weeks After Last Dose, Post Allergen Challenge [units: 10^6 cells/g] Geometric Mean (Full Range)		0.56 (0.087 to 1.8)	0.74 (0.083 to 4.0)

79. Secondary Outcome Measure:

Measure Title	Sputum Cellularity and Cytokines, Lymphocytes - Pre-treatment, Pre Allergen Challenge
Measure Description	
Time Frame	Pre-treatment, pre allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description	
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.	
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.	
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.	

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	12	19
Sputum Cellularity and Cytokines, Lymphocytes - Pretreatment, Pre Allergen Challenge [units: 10^6 cells/g] Geometric Mean (Full Range)		0.004 (0.002 to 0.027)	0.004 (0.002 to 0.059)

Measure Title	Sputum Cellularity and Cytokines, Lymphocytes - Pre-treatment, Post Allergen Challenge
Measure Description	
Time Frame	Pre-treatment, post allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description	
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.	
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.	
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.	

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	17	17
Sputum Cellularity and Cytokines, Lymphocytes - Pretreatment, Post Allergen Challenge [units: 10^6 cells/g] Geometric Mean (Full Range)		0.008 (0.002 to 0.086)	0.004 (0.002 to 0.060)

81. Secondary Outcome Measure:

Measure Title	Sputum Cellularity and Cytokines, Lymphocytes - 1 Week After Last Dose, Pre Allergen Challenge
Measure Description	
Time Frame	1 week after last dose, pre allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description	
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.	
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.	
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.	

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	16	19
Sputum Cellularity and Cytokines, Lymphocytes - 1 Week After Last Dose, Pre Allergen Challenge [units: 10^6 cells/g] Geometric Mean (Full Range)		0.002 (0.002 to 0.016)	0.003 (0.002 to 0.046)

82. Secondary Outcome Measure:

Measure Title	Sputum Cellularity and Cytokines, Lymphocytes - 1 Week After Last Dose, Post Allergen Challenge
Measure Description	
Time Frame	1 week after last dose, post allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	17	17

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Sputum Cellularity and Cytokines, Lymphocytes - 1 Week After Last Dose, Post Allergen Challenge [units: 10^6 cells/g] Geometric Mean (Full Range)		0.003 (0.002 to 0.040)	0.003 (0.002 to 0.045)

Measure Title	Sputum Cellularity and Cytokines, Lymphocytes - 4 Weeks After Last Dose, Pre Allergen Challenge
Measure Description	
Time Frame	4 weeks after last dose, pre allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	16	16
Sputum Cellularity and Cytokines, Lymphocytes - 4 Weeks After Last Dose, Pre Allergen Challenge [units: 10^6 cells/g] Geometric Mean (Full Range)		0.005 (0.002 to 0.035)	0.005 (0.002 to 0.036)

84. Secondary Outcome Measure:

Measure Title	Sputum Cellularity and Cytokines, Lymphocytes - 4 Weeks After Last Dose, Post Allergen Challenge
Measure Description	

Time Frame	4 weeks after last dose, post allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	13	16
Sputum Cellularity and Cytokines, Lymphocytes - 4 Weeks After Last Dose, Post Allergen Challenge [units: 10^6 cells/g] Geometric Mean (Full Range)		0.005 (0.002 to 0.049)	0.003 (0.002 to 0.012)

85. Secondary Outcome Measure:

Measure Title	Sputum Cellularity and Cytokines, Epithelial Cells - Pre-treatment, Pre Allergen Challenge
Measure Description	
Time Frame	Pre-treatment, pre allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.

	Description
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	12	19
Sputum Cellularity and Cytokines, Epithelial Cells - Pre-treatment, Pre Allergen Challenge [units: 10^6 cells/g] Geometric Mean (Full Range)		0.045 (0.001 to 0.29)	0.053 (0.001 to 0.59)

86. Secondary Outcome Measure:

Measure Title	Sputum Cellularity and Cytokines, Epithelial Cells - Pre-treatment, Post Allergen Challenge
Measure Description	
Time Frame	Pre-treatment, post allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description	
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.	
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.	
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.	

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	17	17
Sputum Cellularity and Cytokines, Epithelial Cells - Pre-treatment, Post Allergen Challenge [units: 10^6 cells/g] Geometric Mean (Full Range)		0.078 (0.001 to 3.5)	0.073 (0.001 to 0.35)

Measure Title	Sputum Cellularity and Cytokines, Epithelial Cells - 1 Week After Last Dose, Pre Allergen Challenge
Measure Description	
Time Frame	1 week after last dose, pre allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description	
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.	
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.	
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.	

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	16	19
Sputum Cellularity and Cytokines, Epithelial Cells - 1 Week After Last Dose, Pre Allergen Challenge [units: 10^6 cells/g] Geometric Mean (Full Range)		0.11 (0.008 to 0.39)	0.045 (0.001 to 1.4)

88. Secondary Outcome Measure:

Measure Title	Sputum Cellularity and Cytokines, Epithelial Cells - 1 Week After Last Dose, Post Allergen Challenge
Measure Description	
Time Frame	1 week after last dose, post allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description	
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.	
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.	
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.	

Measured Values

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	17	17
Sputum Cellularity and Cytokines, Epithelial Cells - 1 Week After Last Dose, Post Allergen Challenge [units: 10^6 cells/g] Geometric Mean (Full Range)		0.067 (0.001 to 0.56)	0.071 (0.001 to 0.47)

89. Secondary Outcome Measure:

Measure Title	Sputum Cellularity and Cytokines, Epithelial Cells - 4 Weeks After Last Dose, Pre Allergen Challenge
Measure Description	
Time Frame	4 weeks after last dose, pre allergen challenge
Safety Issue?	No

Analysis Population Description [Not Specified]

Reporting Groups

	Description		
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.		
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.		
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.		

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	16	16

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Sputum Cellularity and Cytokines, Epithelial Cells - 4 Weeks After Last Dose, Pre Allergen Challenge [units: 10^6 cells/g] Geometric Mean (Full Range)		0.045 (0.005 to 0.20)	0.054 (0.001 to 0.43)

Measure Title	Sputum Cellularity and Cytokines, Epithelial Cells - 4 Weeks After Last Dose, Post Allergen Challenge	
Measure Description		
Time Frame	4 weeks after last dose, post allergen challenge	
Safety Issue?	No	

Analysis Population Description [Not Specified]

Reporting Groups

	Description		
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.		
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.		
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.		

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
Number of Participants Analyzed	0	13	16
Sputum Cellularity and Cytokines, Epithelial Cells - 4 Weeks After Last Dose, Post Allergen Challenge [units: 10^6 cells/g] Geometric Mean (Full Range)		0.037 (0.001 to 0.17)	0.082 (0.018 to 0.24)

Reported Adverse Events

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

Reporting Groups

	Description		
AZD8848, 30 μg	AZD8848 nasal spray, 30 μg, one spray in the left nostril once weekly. Pilot part.		
AZD8848, 60 μg	AZD8848 nasal spray, 60 μg, one spray of 30 μg per nostril once weekly. Main part.		
Placebo	Placebo nasal spray, one spray in the left nostril (Pilot part) or per nostril (Main part) once weekly.		

Serious Adverse Events

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	0/	0/	1/
Infections and infestations			
Tonsillitis Bacterial A †	0/6 (0%)	0/26 (0%)	1/28 (3.57%)

[†] Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 13.1

Other Adverse Events

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

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo	
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	
Total	6/	22/	24/	
Ear and labyrinth disorders	Ear and labyrinth disorders			
TINNITUS A †	1/6 (16.67%)	0/26 (0%)	1/28 (3.57%)	
Eye disorders				
EYE SWELLING ^A †	1/6 (16.67%)	0/26 (0%)	0/28 (0%)	
Eye Pruritus ^A †	0/6 (0%)	0/26 (0%)	2/28 (7.14%)	

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
LACRIMATION INCREASED A †	0/6 (0%)	0/26 (0%)	2/28 (7.14%)
Gastrointestinal disorders			
Dysphagia ^A †	1/6 (16.67%)	0/26 (0%)	0/28 (0%)
GLOSSODYNIA ^A †	1/6 (16.67%)	0/26 (0%)	0/28 (0%)
SWOLLEN TONGUE A †	1/6 (16.67%)	0/26 (0%)	0/28 (0%)
General disorders			
CHEST DISCOMFORT A †	0/6 (0%)	2/26 (7.69%)	2/28 (7.14%)
PYREXIA ^A †	2/6 (33.33%)	4/26 (15.38%)	2/28 (7.14%)
Pain ^A †	0/6 (0%)	1/26 (3.85%)	2/28 (7.14%)
Immune system disorders			
ALLERGY TO ARTHROPOD BITE A †	0/6 (0%)	2/26 (7.69%)	0/28 (0%)
Infections and infestations			
NASAL VESTIBULITIS ^A †	1/6 (16.67%)	0/26 (0%)	0/28 (0%)
NASOPHARYNGITIS ^A †	1/6 (16.67%)	2/26 (7.69%)	4/28 (14.29%)
RHINITIS ^A †	0/6 (0%)	2/26 (7.69%)	5/28 (17.86%)
Injury, poisoning and procedural complications			
FACE INJURY A †	1/6 (16.67%)	0/26 (0%)	0/28 (0%)
Musculoskeletal and connective tissue disorde	ers		
ARTHRALGIA ^A †	1/6 (16.67%)	3/26 (11.54%)	1/28 (3.57%)
BACK PAIN ^A †	1/6 (16.67%)	1/26 (3.85%)	0/28 (0%)
PAIN IN EXTREMITY A †	1/6 (16.67%)	0/26 (0%)	0/28 (0%)
Nervous system disorders		·	
DIZZINESS A †	1/6 (16.67%)	1/26 (3.85%)	0/28 (0%)

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
DYSGEUSIA ^A †	1/6 (16.67%)	0/26 (0%)	0/28 (0%)
HEADACHE ^A †	4/6 (66.67%)	15/26 (57.69%)	12/28 (42.86%)
LETHARGY ^A †	1/6 (16.67%)	0/26 (0%)	0/28 (0%)
Respiratory, thoracic and mediastinal disorder	'S		
ASTHMA ^A †	0/6 (0%)	4/26 (15.38%)	4/28 (14.29%)
COUGH ^A †	1/6 (16.67%)	2/26 (7.69%)	7/28 (25%)
EPISTAXIS ^A †	4/6 (66.67%)	3/26 (11.54%)	2/28 (7.14%)
NASAL CONGESTION ^A †	0/6 (0%)	3/26 (11.54%)	2/28 (7.14%)
NASAL DISCOMFORT ^A †	3/6 (50%)	1/26 (3.85%)	4/28 (14.29%)
NASAL DRYNESS ^A †	0/6 (0%)	2/26 (7.69%)	2/28 (7.14%)
NASAL INFLAMMATION ^A †	1/6 (16.67%)	0/26 (0%)	0/28 (0%)
NASAL MUCOSAL DISORDER ^A †	3/6 (50%)	0/26 (0%)	0/28 (0%)
NASAL SEPTUM ULCERATION A †	2/6 (33.33%)	0/26 (0%)	0/28 (0%)
OROPHARYNGEAL PAIN ^A †	2/6 (33.33%)	5/26 (19.23%)	8/28 (28.57%)
RHINORRHOEA ^A †	4/6 (66.67%)	2/26 (7.69%)	4/28 (14.29%)
SNEEZING ^A †	2/6 (33.33%)	2/26 (7.69%)	1/28 (3.57%)
SPUTUM DISCOLOURED A †	0/6 (0%)	0/26 (0%)	2/28 (7.14%)
THROAT IRRITATION ^A †	1/6 (16.67%)	1/26 (3.85%)	0/28 (0%)
UPPER AIRWAY OBSTRUCTION A †	4/6 (66.67%)	0/26 (0%)	0/28 (0%)
WHEEZING ^A †	1/6 (16.67%)	1/26 (3.85%)	4/28 (14.29%)
Skin and subcutaneous tissue disorders			
ERYTHEMA ^A †	2/6 (33.33%)	0/26 (0%)	1/28 (3.57%)

	AZD8848, 30 μg	AZD8848, 60 μg	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
RASH ^A †	1/6 (16.67%)	2/26 (7.69%)	2/28 (7.14%)

[†] Indicates events were collected by systematic assessment.

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.

There is an agreement between PI and Sponsor (AZ) or its agents that restricts the PI's right to discuss/publish trial results after the trial is completed. The PI agrees to collaborate in good faith with AZ with regards to content and formation of any publication or disclosure to be made by PI and to pay due consideration to opinions offered by AZ

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