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Trial record **1 of 1** for: CQAB149B2335S

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26 Week Efficacy, Safety and Tolerability Study of Indacaterol in Patients With Chronic Obstructive Pulmonary Disease (COPD)

This study has been completed.

Sponsor:
Novartis

Information provided by:
Novartis

ClinicalTrials.gov Identifier:
NCT00463567

First received: April 19, 2007
Last updated: July 22, 2011
Last verified: July 2011
History of Changes

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Results First Received: July 22, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Conditions:	Pulmonary Disease, Chronic Obstructive COPD Lung Diseases, Obstructive
	Drug: Indacaterol

Interventions:	Drug: Formoterol (12 µg b.i.d.) Drug: Tiotropium (18 µg o.d.) Drug: Placebo to Indacaterol Drug: Placebo to Formoterol

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
This study consisted of two stages: a dose selection stage (Stage 1, 2 weeks) from which 2 out of 4 Indacaterol doses were selected following interim analysis to continue into Stage 2 for comparisons of efficacy, safety, and tolerability for total treatment of up to 26 weeks.

Reporting Groups

	Description
Indacaterol 150 µg (Continued Into Stage 2)	In the morning, Indacaterol 150 µg once daily orally inhaled via a single dose dry powder inhaler (SDDPI) + Placebo to Indacaterol delivered via SDDPI + Placebo to Formoterol delivered via Aerolizer. In the evening, Placebo to Formoterol delivered via Aerolizer. Participated in the 2 week Stage 1 and continued treatment up to 26 weeks in Stage 2. Placebo to Formoterol inhalation in the morning and in the evening was discontinued after Stage 1. Daily Inhaled Corticosteroid (ICS) monotherapy (if applicable) was to remain stable and Salbutamol/albuterol was available for rescue use throughout study.
Indacaterol 300 µg (Continued Into Stage 2)	In the morning, Indacaterol 300 µg once daily orally inhaled via a SDDPI + Placebo to Indacaterol delivered via SDDPI + Placebo to Formoterol delivered via Aerolizer. In evening, Placebo to Formoterol delivered via Aerolizer. Participated in the 2 week Stage 1 and continued treatment up to 26 weeks in Stage 2. Placebo to Formoterol inhalation in the

	morning and in the evening was discontinued after Stage 1. Daily ICS monotherapy (if applicable) was to remain stable and Salbutamol/albuterol was available for rescue use throughout study.
Tiotropium (Continued Into Stage 2)	Tiotropium 18 µg dry powder capsules delivered (open label) via manufacturer's proprietary SDDPI, (Handihaler®). Participated in the 2 week Stage 1 and continued treatment up to 26 weeks in Stage 2. Daily ICS monotherapy (if applicable) was to remain stable and Salbutamol/albuterol was available for rescue use throughout study.
Placebo (Continued Into Stage 2)	In the morning, Placebo to Indacaterol delivered via two SDDPI devices + Placebo to Formoterol delivered via Aerolizer. In the evening, Placebo to Formoterol delivered via Aerolizer. Participated in the 2 week Stage 1 and continued treatment up to 26 weeks in Stage 2. Placebo to Formoterol inhalation in the morning and in the evening was discontinued after Stage 1. Daily ICS monotherapy (if applicable) was to remain stable and Salbutamol/albuterol was available for rescue use throughout study.
Indacaterol 75 µg (Not Continued Into Stage 2)	In the morning, Indacaterol 75 µg once daily orally inhaled via a SDDPI + Placebo to Indacaterol delivered via SDDPI + Placebo to Formoterol delivered via Aerolizer. In the evening, Placebo to Formoterol delivered via Aerolizer. Participated in the 2 week Stage 1 but did not continue to Stage 2. Daily ICS monotherapy (if applicable) was to remain stable and Salbutamol/albuterol was available for rescue use throughout study.
Indacaterol 600 µg (Not Continued Into Stage 2)	In the morning, 2 capsules of Indacaterol 300 µg once daily orally inhaled via two SDDPI devices + Placebo to Formoterol delivered via Aerolizer. In the evening, Placebo to Formoterol delivered via Aerolizer. Participated in the 2 week Stage 1 but did not continue to Stage 2. Daily ICS monotherapy (if applicable) was to remain stable and Salbutamol/albuterol was available for rescue use throughout study.
Formoterol 12 µg (Not Continued Into Stage 2)	In the morning, Placebo to Indacaterol delivered via two SDDPI devices + Formoterol 12 µg delivered via Aerolizer. In evening, Formoterol 12 µg delivered via Aerolizer. Participated in the 2 week Stage 1 but did not continue to Stage 2. Daily ICS monotherapy (if applicable) was to remain stable and Salbutamol/albuterol was

	available for rescue use throughout study.

Participant Flow: Overall Study

	Indacaterol 150 µg (Continued Into Stage 2)	Indacaterol 300 µg (Continued Into Stage 2)	Tiotropium (Continued Into Stage 2)	Placebo (Continued Into Stage 2)	Indacaterol 75 µg (Not Continued Into Stage 2)	Indacaterol 600 µg (Not Continued Into Stage 2)	Formoterol 12 µg (Not Continued Into Stage 2)
STARTED	420 [1]	418	420	425	130	123	123
Safety Population: Received Study Drug	416	416	415	418	127 [2]	122 [2]	122 [2]
COMPLETED	325	341	331	294	107	102	112
NOT COMPLETED	95	77	89	131	23	21	11
Adverse Event	29	26	17	46	10	10	4
Withdrawal by Subject	29	22	20	37	6	5	1
Protocol Deviation	13	9	14	11	1	1	2
Lost to Follow-up	12	6	13	8	1	1	1
Administrative problems	5	3	6	9	3	2	2
Lack of Efficacy	4	9	9	17	1	0	1
Abnormal lab value(s)	1	1	2	1	1	0	0
Abnormal test							

procedure result(s)	**1**	**1**	**6**	**2**	**0**	**2**	**0**
Death	**1**	**0**	**2**	**0**	**0**	**0**	**0**

[1] Randomized Participants
[2] 'Completed' indicates the number of patients in the interim analysis.

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Indacaterol 150 µg (Continued Into Stage 2)	In the morning, Indacaterol 150 µg once daily orally inhaled via a single dose dry powder inhaler (SDDPI) + Placebo to Indacaterol delivered via SDDPI + Placebo to Formoterol delivered via Aerolizer. In the evening, Placebo to Formoterol delivered via Aerolizer. Participated in the 2 week Stage 1 and continued treatment up to 26 weeks in Stage 2. Placebo to Formoterol inhalation in the morning and in the evening was discontinued after Stage 1. Daily Inhaled Corticosteroid (ICS) monotherapy (if applicable) was to remain stable and Salbutamol/albuterol was available for rescue use throughout study.
Indacaterol 300 µg (Continued Into Stage 2)	In the morning, Indacaterol 300 µg once daily orally inhaled via a SDDPI + Placebo to Indacaterol delivered via SDDPI + Placebo to Formoterol delivered via Aerolizer. In evening, Placebo to Formoterol delivered via Aerolizer. Participated in the 2 week Stage 1 and continued treatment up to 26 weeks in Stage 2. Placebo to Formoterol inhalation in the morning and in the evening was discontinued after Stage 1. Daily ICS monotherapy (if applicable) was to remain stable and Salbutamol/albuterol was available for rescue use throughout study.

Tiotropium 18 µg (Continued Into Stage 2)	Tiotropium 18 µg dry powder capsules delivered (open label) via manufacturer's proprietary SDDPI, (Handihaler®). Participated in the 2 week Stage 1 and continued treatment up to 26 weeks in Stage 2. Daily ICS monotherapy (if applicable) was to remain stable and Salbutamol/albuterol was available for rescue use throughout study.
Placebo (Continued Into Stage 2)	In the morning, Placebo to Indacaterol delivered via two SDDPI devices + Placebo to Formoterol delivered via Aerolizer. In the evening, Placebo to Formoterol delivered via Aerolizer. Participated in the 2 week Stage 1 and continued treatment up to 26 weeks in Stage 2. Placebo to Formoterol inhalation in the morning and in the evening was discontinued after Stage 1. Daily ICS monotherapy (if applicable) was to remain stable and Salbutamol/albuterol was available for rescue use throughout study.
Indacaterol 75 µg (Not Continued Into Stage 2)	In the morning, Indacaterol 75 µg once daily orally inhaled via a SDDPI + Placebo to Indacaterol delivered via SDDPI + Placebo to Formoterol delivered via Aerolizer. In the evening, Placebo to Formoterol delivered via Aerolizer. Participated in the 2 week Stage 1 but did not continue to Stage 2. Daily ICS monotherapy (if applicable) was to remain stable and Salbutamol/albuterol was available for rescue use throughout study.
Indacaterol 600 µg (Not Continued Into Stage 2)	In the morning, 2 capsules of Indacaterol 300 µg once daily orally inhaled via two SDDPI devices + Placebo to Formoterol delivered via Aerolizer. In the evening, Placebo to Formoterol delivered via Aerolizer. Participated in the 2 week Stage 1 but did not continue to Stage 2. Daily ICS monotherapy (if applicable) was to remain stable and Salbutamol/albuterol was available for rescue use throughout study.
Formoterol 12 µg (Not Continued Into Stage 2)	In the morning, Placebo to Indacaterol delivered via two SDDPI devices + Formoterol 12 µg delivered via Aerolizer. In evening, Formoterol 12 µg delivered via Aerolizer. Participated in the 2 week Stage 1 but did not continue to Stage 2. Daily ICS monotherapy (if applicable) was to remain stable and Salbutamol/albuterol was available for rescue use throughout study.
Total	Total of all reporting groups

Baseline Measures

	Indacaterol 150 µg (Continued Into Stage 2)	Indacaterol 300 µg (Continued Into Stage 2)	Tiotropium 18 µg (Continued Into Stage 2)	Placebo (Continued Into Stage 2)	Indacaterol 75 µg (Not Continued Into Stage 2)	Indacaterol 600 µg (Not Continued Into Stage 2)	Formoterol 12 µg (Not Continued Into Stage 2)	Total
Number of Participants [units: participants]	416	416	415	418	127	122	122	2036
Age, Customized [1] [units: participants]								
Between 40 and 64 years	214	230	215	215	58	60	56	1048
≥65 years	202	186	200	203	69	62	66	988
Gender [units: participants]								
Female	157	153	146	163	51	48	52	770
Male	259	263	269	255	76	74	70	1266

[1] Baseline Measures were based on the Safety Population that included all participants who received at least one dose of study drug.

Outcome Measures

Hide All Outcome Measures

1. Primary: Trough Forced Expiratory Volume in 1 Second (FEV1) Assessed by Spirometry 24 Hour Post Dose After 12 Weeks of Treatment [

Time Frame: after 12 weeks of treatment]

Measure Type	Primary
Measure Title	Trough Forced Expiratory Volume in 1 Second (FEV1) Assessed by Spirometry 24 Hour Post Dose After 12 Weeks of Treatment
Measure Description	FEV1 was measured with spirometry conducted according to internationally accepted standards. Trough FEV1 was defined as the average of the 23 h 10 min and the 23 h 45 min post dose values. Mixed model used baseline FEV1, FEV1 prior to and 30 minutes post inhalation of salbutamol/albuterol, and FEV1 prior to and 1 hour post inhalation of ipratropium as covariates.
Time Frame	after 12 weeks of treatment
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants from the Intent to Treat Population of Stage 2 of the study who received at least one dose of study drug and for whom data was available for FEV1 at 12 weeks. Imputed with last observation carried forward.

Reporting Groups

	Description
Indacaterol 150 µg (Continued Into Stage 2)	In the morning, Indacaterol 150 µg once daily orally inhaled via a single dose dry powder inhaler (SDDPI) + Placebo to Indacaterol delivered via SDDPI + Placebo to Formoterol delivered via Aerolizer. In the evening, Placebo to Formoterol delivered via Aerolizer. Participated in the 2 week Stage 1 and continued treatment up to 26 weeks in Stage 2. Placebo to Formoterol inhalation in the morning and in the evening was discontinued after Stage 1. Daily Inhaled Corticosteroid (ICS) monotherapy (if applicable) was to remain stable and Salbutamol/albuterol was available for rescue use throughout study.
Indacaterol 300 µg (Continued Into Stage 2)	In the morning, Indacaterol 300 µg once daily orally inhaled via a SDDPI + Placebo to Indacaterol delivered via SDDPI + Placebo to Formoterol delivered via Aerolizer. In evening, Placebo to Formoterol delivered via Aerolizer. Participated in the 2 week Stage 1 and continued treatment up to 26 weeks in Stage 2. Placebo to Formoterol inhalation in the morning and in the

	evening was discontinued after Stage 1. Daily ICS monotherapy (if applicable) was to remain stable and Salbutamol/albuterol was available for rescue use throughout study.
Tiotropium 18 µg (Continued Into Stage 2)	Tiotropium 18 µg dry powder capsules delivered (open label) via manufacturer's proprietary SDDPI, (Handihaler®). Participated in the 2 week Stage 1 and continued treatment up to 26 weeks in Stage 2. Daily ICS monotherapy (if applicable) was to remain stable and Salbutamol/albuterol was available for rescue use throughout study.
Placebo (Continued Into Stage 2)	In the morning, Placebo to Indacaterol delivered via two SDDPI devices + Placebo to Formoterol delivered via Aerolizer. In the evening, Placebo to Formoterol delivered via Aerolizer. Participated in the 2 week Stage 1 and continued treatment up to 26 weeks in Stage 2. Placebo to Formoterol inhalation in the morning and in the evening was discontinued after Stage 1. Daily ICS monotherapy (if applicable) was to remain stable and Salbutamol/albuterol was available for rescue use throughout study.

Measured Values

	Indacaterol 150 µg (Continued Into Stage 2)	Indacaterol 300 µg (Continued Into Stage 2)	Tiotropium 18 µg (Continued Into Stage 2)	Placebo (Continued Into Stage 2)
Number of Participants Analyzed [units: participants]	**389**	**389**	**393**	**376**
Trough Forced Expiratory Volume in 1 Second (FEV1) Assessed by Spirometry 24 Hour Post Dose After 12 Weeks of Treatment [units: Liters] Least Squares Mean (Standard Error)	**1.46 (0.015)**	**1.46 (0.015)**	**1.42 (0.015)**	**1.28 (0.015)**

No statistical analysis provided for Trough Forced Expiratory Volume in 1 Second (FEV1) Assessed by Spirometry 24 Hour Post Dose After 12 Weeks of Treatment

2. Secondary: The Percentage of "Days of Poor Control" Reported Over the 26 Week Treatment Period [Time Frame: up to 26 weeks]

Measure Type	Secondary
Measure Title	The Percentage of "Days of Poor Control" Reported Over the 26 Week Treatment Period
Measure Description	A Chronic Obstructive Pulmonary Disease (COPD) "day of poor control" was defined as any day in the participant's diary with a score ≥2 (moderate or severe) for at least 2 of 5 symptoms (cough, wheeze, production of sputum, color of sputum, breathlessness). Score for each symptom ranges from 0-3; a higher number indicates a more severe symptom. The model contained baseline percentage of “days of poor control” as well as FEV1 reversibility components as covariates.
Time Frame	up to 26 weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent to Treat population consisting of all participants in Stage 2 of the study who received at least one dose of study drug. Eligible participants for the analysis were those with ≥7 evaluable diary days in the baseline period and ≥30% evaluable diary days (at least 20 days) in total.

Reporting Groups

	Description
Indacaterol 150 µg (Continued Into Stage 2)	In the morning, Indacaterol 150 µg once daily orally inhaled via a single dose dry powder inhaler (SDDPI) + Placebo to Indacaterol delivered via SDDPI + Placebo to Formoterol delivered via Aerolizer. In the evening, Placebo to Formoterol delivered via Aerolizer. Participated in the 2 week Stage 1 and continued treatment up to 26 weeks in Stage 2. Placebo to Formoterol inhalation in the morning and in the evening was discontinued after Stage 1. Daily Inhaled Corticosteroid (ICS) monotherapy (if applicable) was to remain stable and Salbutamol/albuterol was available for rescue use throughout study.
Indacaterol 300 µg (Continued Into Stage 2)	In the morning, Indacaterol 300 µg once daily orally inhaled via a SDDPI + Placebo to Indacaterol delivered via SDDPI + Placebo to Formoterol delivered via Aerolizer. In evening, Placebo to Formoterol delivered via Aerolizer. Participated in the 2 week Stage 1 and continued

	treatment up to 26 weeks in Stage 2. Placebo to Formoterol inhalation in the morning and in the evening was discontinued after Stage 1. Daily ICS monotherapy (if applicable) was to remain stable and Salbutamol/albuterol was available for rescue use throughout study.
Tiotropium (Continued Into Stage 2)	Tiotropium 18 µg dry powder capsules delivered (open label) via manufacturer's proprietary SDDPI, (Handihaler®). Participated in the 2 week Stage 1 and continued treatment up to 26 weeks in Stage 2. Daily ICS monotherapy (if applicable) was to remain stable and Salbutamol/albuterol was available for rescue use throughout study.
Placebo (Continued Into Stage 2)	In the morning, Placebo to Indacaterol delivered via two SDDPI devices + Placebo to Formoterol delivered via Aerolizer. In the evening, Placebo to Formoterol delivered via Aerolizer. Participated in the 2 week Stage 1 and continued treatment up to 26 weeks in Stage 2. Placebo to Formoterol inhalation in the morning and in the evening was discontinued after Stage 1. Daily ICS monotherapy (if applicable) was to remain stable and Salbutamol/albuterol was available for rescue use throughout study.

Measured Values

	Indacaterol 150 µg (Continued Into Stage 2)	Indacaterol 300 µg (Continued Into Stage 2)	Tiotropium (Continued Into Stage 2)	Placebo (Continued Into Stage 2)
Number of Participants Analyzed [units: participants]	**385**	**384**	**391**	**362**
The Percentage of "Days of Poor Control" Reported Over the 26 Week Treatment Period [units: Percentage of days] Least Squares Mean (Standard Error)	**31.5 (1.51)**	**30.8 (1.51)**	**31.0 (1.50)**	**34.0 (1.53)**

No statistical analysis provided for The Percentage of "Days of Poor Control" Reported Over the 26 Week Treatment Period

3. Other Pre-specified: Trough Forced Expiratory Volume in 1 Second (FEV1) Assessed by Spirometry 24 Hour Post Dose After 2 Weeks of

Treatment [Time Frame: Day 15, After 2 Weeks of treatment in Stage 1]

Measure Type	Other Pre-specified
Measure Title	Trough Forced Expiratory Volume in 1 Second (FEV1) Assessed by Spirometry 24 Hour Post Dose After 2 Weeks of Treatment
Measure Description	Interim Analysis: Stage 1. Spirometry was conducted according to internationally accepted standards. Trough FEV1 was defined as the average of the 23 h 10 min and the 23 h 45 min post dose values. Mixed model used baseline FEV1, FEV1 prior to and 30 minutes post inhalation of salbutamol/albuterol, and FEV1 prior to and 1 hour post inhalation of ipratropium as covariates.
Time Frame	Day 15, After 2 Weeks of treatment in Stage 1
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Interim Intent-to-treat (ITT) population included participants in Stage 1 of the study who received at least one dose of study drug and for whom data were available for Trough FEV1 at Day 15. Missing data were imputed using last observation carried forward (LOCF).

Reporting Groups

	Description
Indacaterol 150 µg	In the morning, Indacaterol 150 µg once daily orally inhaled via a SDDPI + Placebo to Indacaterol delivered via SDDPI + Placebo to Formoterol delivered via Aerolizer. In the evening, Placebo to Formoterol delivered via Aerolizer. Daily ICS monotherapy (if applicable) was to remain stable and Salbutamol/albuterol was available for rescue use throughout study.
Indacaterol 300 µg	In the morning, Indacaterol 300 µg once daily orally inhaled via a SDDPI + Placebo to Indacaterol delivered via SDDPI + Placebo to Formoterol delivered via Aerolizer. In evening, Placebo to Formoterol delivered via Aerolizer. Daily ICS monotherapy (if applicable) was to remain stable and Salbutamol/albuterol was available for rescue use throughout study.

Tiotropium 18 µg	Tiotropium 18 µg dry powder capsules delivered (open label) via manufacturer's proprietary SDDPI, (Handihaler®). Daily ICS monotherapy (if applicable) was to remain stable and Salbutamol/albuterol was available for rescue use throughout study.
Placebo	In the morning, Placebo to Indacaterol delivered via two SDDPI devices + Placebo to Formoterol delivered via Aerolizer. In evening, Placebo to Formoterol delivered via Aerolizer. Daily ICS monotherapy (if applicable) was to remain stable and Salbutamol/albuterol was available for rescue use throughout study.
Indacaterol 75 µg	In the morning, Indacaterol 75 µg once daily orally inhaled via a SDDPI + Placebo to Indacaterol delivered via SDDPI + Placebo to Formoterol delivered via Aerolizer. In the evening, Placebo to Formoterol delivered via Aerolizer. Daily ICS monotherapy (if applicable) was to remain stable and Salbutamol/albuterol was available for rescue use throughout study.
Indacaterol 600 µg	In the morning, 2 capsules of Indacaterol 300 µg once daily orally inhaled via two SDDPI devices + Placebo to Formoterol delivered via Aerolizer. In the evening, Placebo to Formoterol delivered via Aerolizer. Daily ICS monotherapy (if applicable) was to remain stable and Salbutamol/albuterol was available for rescue use throughout study.
Formoterol 12 µg	In the morning, Placebo to Indacaterol delivered via two SDDPI devices + Formoterol 12 µg delivered via Aerolizer. In evening, Formoterol 12 µg delivered via Aerolizer. Daily ICS monotherapy (if applicable) was to remain stable and Salbutamol/albuterol was available for rescue use throughout study.

Measured Values

	Indacaterol 150 µg	Indacaterol 300 µg	Tiotropium 18 µg	Placebo	Indacaterol 75 µg	Indacaterol 600 µg	Formoterol 12 µg
Number of Participants Analyzed [units: participants]	**105**	**110**	**112**	**104**	**104**	**108**	**105**
Trough Forced Expiratory Volume in 1 Second (FEV1) Assessed by Spirometry 24 Hour Post Dose After 2 Weeks of Treatment [units: Liters]	**1.49 (0.024)**	**1.52 (0.024)**	**1.45 (0.023)**	**1.31 (0.024)**	**1.46 (0.024)**	**1.51 (0.024)**	**1.42 (0.024)**

Least Squares Mean (Standard Error)							

No statistical analysis provided for Trough Forced Expiratory Volume in 1 Second (FEV1) Assessed by Spirometry 24 Hour Post Dose After 2 Weeks of Treatment

4. Other Pre-specified: Forced Expiratory Volume in 1 Second (FEV1) Standardized (With Respect to Time) Area Under the Curve (AUC) From 1 Hour to 4 Hour Post Morning Dose After 2 Weeks of Treatment [Time Frame: Day 14, After 2 Weeks of treatment in Stage 1]

Measure Type	Other Pre-specified
Measure Title	Forced Expiratory Volume in 1 Second (FEV1) Standardized (With Respect to Time) Area Under the Curve (AUC) From 1 Hour to 4 Hour Post Morning Dose After 2 Weeks of Treatment
Measure Description	Interim Analysis: Stage 1. Spirometry was conducted according to internationally accepted standards. Standardized with respect to time (AUC 1h-4h) for FEV1 measurements taken from 1 hour to 4 hour post morning dose on Day 14. Standardized FEV1 AUC was calculated by the trapezoidal rule. Mixed model used baseline FEV1, FEV1 prior to and 30 minutes post inhalation of salbutamol/albuterol, and FEV1 prior to and 1 hour post inhalation of ipratropium as covariates.
Time Frame	Day 14, After 2 Weeks of treatment in Stage 1
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Interim Intent-to-treat (ITT) population included participants in Stage 1 of the study who received at least one dose of study drug and for whom data were available for AUC 1h-4h FEV1 at Day 14. Missing data were imputed using last observation carried forward (LOCF).

Reporting Groups

	Description
Indacaterol 150 µg	In the morning, Indacaterol 150 µg once daily orally inhaled via a SDDPI + Placebo to Indacaterol delivered via SDDPI +

	Placebo to Formoterol delivered via Aerolizer. In the evening, Placebo to Formoterol delivered via Aerolizer. Daily ICS monotherapy (if applicable) was to remain stable and Salbutamol/albuterol was available for rescue use throughout study.
Indacaterol 300 µg	In the morning, Indacaterol 300 µg once daily orally inhaled via a SDDPI + Placebo to Indacaterol delivered via SDDPI + Placebo to Formoterol delivered via Aerolizer. In evening, Placebo to Formoterol delivered via Aerolizer. Daily ICS monotherapy (if applicable) was to remain stable and Salbutamol/albuterol was available for rescue use throughout study.
Tiotropium 18 µg	Tiotropium 18 µg dry powder capsules delivered (open label) via manufacturer's proprietary SDDPI, (Handihaler®). Daily ICS monotherapy (if applicable) was to remain stable and Salbutamol/albuterol was available for rescue use throughout study.
Placebo	In the morning, Placebo to Indacaterol delivered via two SDDPI devices + Placebo to Formoterol delivered via Aerolizer. In evening, Placebo to Formoterol delivered via Aerolizer. Daily ICS monotherapy (if applicable) was to remain stable and Salbutamol/albuterol was available for rescue use throughout study.
Indacaterol 75 µg	In the morning, Indacaterol 75 µg once daily orally inhaled via a SDDPI + Placebo to Indacaterol delivered via SDDPI + Placebo to Formoterol delivered via Aerolizer. In the evening, Placebo to Formoterol delivered via Aerolizer. Daily ICS monotherapy (if applicable) was to remain stable and Salbutamol/albuterol was available for rescue use throughout study.
Indacaterol 600 µg	In the morning, 2 capsules of Indacaterol 300 µg once daily orally inhaled via two SDDPI devices + Placebo to Formoterol delivered via Aerolizer. In the evening, Placebo to Formoterol delivered via Aerolizer. Daily ICS monotherapy (if applicable) was to remain stable and Salbutamol/albuterol was available for rescue use throughout study.
Formoterol 12 µg	In the morning, Placebo to Indacaterol delivered via SDDPI devices + Formoterol 12 µg delivered via Aerolizer. In evening, Formoterol 12 µg delivered via Aerolizer. Daily ICS monotherapy (if applicable) was to remain stable and Salbutamol/albuterol was available for rescue use throughout study.

Measured Values

	Indacaterol 150 µg	Indacaterol 300 µg	Tiotropium 18 µg	Placebo	Indacaterol 75 µg	Indacaterol 600 µg	Formoterol 12 µg
Number of Participants Analyzed [units: participants]	**96**	**99**	**99**	**90**	**95**	**97**	**93**
Forced Expiratory Volume in 1 Second (FEV1) Standardized (With Respect to Time) Area Under the Curve (AUC) From 1 Hour to 4 Hour Post Morning Dose After 2 Weeks of Treatment [units: Liters] Least Squares Mean (Standard Error)	**1.53 (0.034)**	**1.58 (0.034)**	**1.49 (0.034)**	**1.30 (0.033)**	**1.50 (0.034)**	**1.53 (0.034)**	**1.52 (0.035)**

No statistical analysis provided for Forced Expiratory Volume in 1 Second (FEV1) Standardized (With Respect to Time) Area Under the Curve (AUC) From 1 Hour to 4 Hour Post Morning Dose After 2 Weeks of Treatment

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	Safety Population including all participants who received at least one dose of study drug.

Reporting Groups

	Description
Indacaterol 150 µg (Continued Into Stage 2)	In the morning, Indacaterol 150 µg once daily orally inhaled via a single dose dry powder inhaler (SDDPI) + Placebo to Indacaterol delivered via SDDPI + Placebo to Formoterol delivered via Aerolizer. In the evening, Placebo to Formoterol delivered via Aerolizer. Participated in the 2 week Stage 1 and continued treatment up to 26 weeks in Stage 2. Placebo to Formoterol inhalation in the morning and in the evening was discontinued after Stage 1. Daily Inhaled Corticosteroid (ICS) monotherapy (if applicable) was to remain stable and Salbutamol/albuterol was available for rescue use throughout study.

Indacaterol 300 µg (Continued Into Stage 2)	In the morning, Indacaterol 300 µg once daily orally inhaled via a SDDPI + Placebo to Indacaterol delivered via SDDPI + Placebo to Formoterol delivered via Aerolizer. In evening, Placebo to Formoterol delivered via Aerolizer. Participated in the 2 week Stage 1 and continued treatment up to 26 weeks in Stage 2. Placebo to Formoterol inhalation in the morning and in the evening was discontinued after Stage 1. Daily ICS monotherapy (if applicable) was to remain stable and Salbutamol/albuterol was available for rescue use throughout study.
Tiotropium 18 µg (Continued Into Stage 2)	Tiotropium 18 µg dry powder capsules delivered (open label) via manufacturer's proprietary SDDPI, (Handihaler®). Participated in the 2 week Stage 1 and continued treatment up to 26 weeks in Stage 2. Daily ICS monotherapy (if applicable) was to remain stable and Salbutamol/albuterol was available for rescue use throughout study.
Placebo (Continued Into Stage 2)	In the morning, Placebo to Indacaterol delivered via two SDDPI devices + Placebo to Formoterol delivered via Aerolizer. In the evening, Placebo to Formoterol delivered via Aerolizer. Participated in the 2 week Stage 1 and continued treatment up to 26 weeks in Stage 2. Placebo to Formoterol inhalation in the morning and in the evening was discontinued after Stage 1. Daily ICS monotherapy (if applicable) was to remain stable and Salbutamol/albuterol was available for rescue use throughout study.
Indacaterol 75 µg (Not Continued Into Stage 2)	In the morning, Indacaterol 75 µg once daily orally inhaled via a SDDPI + Placebo to Indacaterol delivered via SDDPI + Placebo to Formoterol delivered via Aerolizer. In the evening, Placebo to Formoterol delivered via Aerolizer. Participated in the 2 week Stage 1 but did not continue to Stage 2. Daily ICS monotherapy (if applicable) was to remain stable and Salbutamol/albuterol was available for rescue use throughout study.
Indacaterol 600 µg (Not Continued Into Stage 2)	In the morning, 2 capsules of Indacaterol 300 µg once daily orally inhaled via two SDDPI devices + Placebo to Formoterol delivered via Aerolizer. In the evening, Placebo to Formoterol delivered via Aerolizer. Participated in the 2 week Stage 1 but did not continue to Stage 2. Daily ICS monotherapy (if applicable) was to remain stable and Salbutamol/albuterol was available for rescue use throughout study.

Formoterol 12 µg (Not Continued Into Stage 2)	In the morning, Placebo to Indacaterol delivered via two SDDPI devices + Formoterol 12 µg delivered via Aerolizer. In evening, Formoterol 12 µg delivered via Aerolizer. Participated in the 2 week Stage 1 but did not continue to Stage 2. Daily ICS monotherapy (if applicable) was to remain stable and Salbutamol/albuterol was available for rescue use throughout study.

Serious Adverse Events

	Indacaterol 150 µg (Continued Into Stage 2)	Indacaterol 300 µg (Continued Into Stage 2)	Tiotropium 18 µg (Continued Into Stage 2)	Placebo (Continued Into Stage 2)	Indacaterol 75 µg (Not Continued Into Stage 2)	Indacaterol 600 µg (Not Continued Into Stage 2)	Formoterol 12 µg (Not Continued Into Stage 2)
Total, serious adverse events							
# participants affected / at risk	**35/416 (8.41%)**	**32/416 (7.69%)**	**34/415 (8.19%)**	**35/418 (8.37%)**	**9/127 (7.09%)**	**5/122 (4.10%)**	**4/122 (3.28%)**
Blood and lymphatic system disorders							
Idiopathic thrombocytopenic purpura † 1							
# participants affected / at risk	**1/416 (0.24%)**	**0/416 (0.00%)**	**0/415 (0.00%)**	**0/418 (0.00%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Microcytic anaemia † 1							
# participants affected / at risk	**0/416 (0.00%)**	**0/416 (0.00%)**	**0/415 (0.00%)**	**0/418 (0.00%)**	**1/127 (0.79%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Cardiac disorders							
Acute coronary syndrome † 1							

# participants affected / at risk	0/416 (0.00%)	0/416 (0.00%)	2/415 (0.48%)	0/418 (0.00%)	0/127 (0.00%)	0/122 (0.00%)	0/122 (0.00%)
Acute myocardial infarction † [1]							
# participants affected / at risk	1/416 (0.24%)	0/416 (0.00%)	0/415 (0.00%)	0/418 (0.00%)	0/127 (0.00%)	0/122 (0.00%)	0/122 (0.00%)
Angina pectoris † [1]							
# participants affected / at risk	2/416 (0.48%)	1/416 (0.24%)	0/415 (0.00%)	1/418 (0.24%)	1/127 (0.79%)	0/122 (0.00%)	0/122 (0.00%)
Angina unstable † [1]							
# participants affected / at risk	0/416 (0.00%)	2/416 (0.48%)	0/415 (0.00%)	0/418 (0.00%)	1/127 (0.79%)	0/122 (0.00%)	0/122 (0.00%)
Arrhythmia supraventricular † [1]							
# participants affected / at risk	0/416 (0.00%)	0/416 (0.00%)	1/415 (0.24%)	0/418 (0.00%)	0/127 (0.00%)	0/122 (0.00%)	0/122 (0.00%)
Atrial fibrillation † [1]							
# participants affected / at risk	3/416 (0.72%)	0/416 (0.00%)	3/415 (0.72%)	2/418 (0.48%)	1/127 (0.79%)	0/122 (0.00%)	0/122 (0.00%)
Atrial flutter † [1]							
# participants affected / at risk	0/416 (0.00%)	0/416 (0.00%)	1/415 (0.24%)	0/418 (0.00%)	0/127 (0.00%)	0/122 (0.00%)	0/122 (0.00%)
Cardiac failure congestive † [1]							
# participants	0/416 (0.00%)	1/416 (0.24%)	0/415 (0.00%)	0/418 (0.00%)	1/127 (0.79%)		0/122 (0.00%)

affected / at risk						**0/122 (0.00%)**	
Coronary artery disease † [1]							
# participants affected / at risk	**1/416 (0.24%)**	**2/416 (0.48%)**	**0/415 (0.00%)**	**1/418 (0.24%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Coronary artery occlusion † [1]							
# participants affected / at risk	**0/416 (0.00%)**	**0/416 (0.00%)**	**2/415 (0.48%)**	**0/418 (0.00%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Ischaemic cardiomyopathy † [1]							
# participants affected / at risk	**0/416 (0.00%)**	**0/416 (0.00%)**	**1/415 (0.24%)**	**0/418 (0.00%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Myocardial infarction † [1]							
# participants affected / at risk	**1/416 (0.24%)**	**0/416 (0.00%)**	**0/415 (0.00%)**	**1/418 (0.24%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Sick sinus syndrome † [1]							
# participants affected / at risk	**0/416 (0.00%)**	**1/416 (0.24%)**	**0/415 (0.00%)**	**0/418 (0.00%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Ventricular tachycardia † [1]							
# participants affected / at risk	**1/416 (0.24%)**	**0/416 (0.00%)**	**0/415 (0.00%)**	**1/418 (0.24%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Congenital, familial and genetic disorders							

Endocardial fibroelastosis † [1]							
# participants affected / at risk	**0/416 (0.00%)**	**0/416 (0.00%)**	**0/415 (0.00%)**	**1/418 (0.24%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Ear and labyrinth disorders							
Deafness neurosensory † [1]							
# participants affected / at risk	**0/416 (0.00%)**	**0/416 (0.00%)**	**1/415 (0.24%)**	**0/418 (0.00%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Eye disorders							
Cataract † [1]							
# participants affected / at risk	**0/416 (0.00%)**	**1/416 (0.24%)**	**0/415 (0.00%)**	**0/418 (0.00%)**	**1/127 (0.79%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Retinal artery occlusion † [1]							
# participants affected / at risk	**0/416 (0.00%)**	**0/416 (0.00%)**	**1/415 (0.24%)**	**0/418 (0.00%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Gastrointestinal disorders							
Abdominal pain lower † [1]							
# participants affected / at risk	**0/416 (0.00%)**	**0/416 (0.00%)**	**0/415 (0.00%)**	**1/418 (0.24%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Diarrhoea † [1]							
# participants							

affected / at risk	0/416 (0.00%)	0/416 (0.00%)	1/415 (0.24%)	0/418 (0.00%)	0/127 (0.00%)	0/122 (0.00%)	0/122 (0.00%)
Dysphagia † [1]							
# participants affected / at risk	0/416 (0.00%)	0/416 (0.00%)	1/415 (0.24%)	0/418 (0.00%)	0/127 (0.00%)	0/122 (0.00%)	0/122 (0.00%)
Faecaloma † [1]							
# participants affected / at risk	0/416 (0.00%)	0/416 (0.00%)	0/415 (0.00%)	1/418 (0.24%)	0/127 (0.00%)	0/122 (0.00%)	0/122 (0.00%)
Ileus paralytic † [1]							
# participants affected / at risk	0/416 (0.00%)	0/416 (0.00%)	0/415 (0.00%)	1/418 (0.24%)	0/127 (0.00%)	0/122 (0.00%)	0/122 (0.00%)
Inguinal hernia † [1]							
# participants affected / at risk	0/416 (0.00%)	0/416 (0.00%)	0/415 (0.00%)	1/418 (0.24%)	0/127 (0.00%)	0/122 (0.00%)	0/122 (0.00%)
Intestinal obstruction † [1]							
# participants affected / at risk	0/416 (0.00%)	0/416 (0.00%)	0/415 (0.00%)	0/418 (0.00%)	0/127 (0.00%)	1/122 (0.82%)	0/122 (0.00%)
Nausea † [1]							
# participants affected / at risk	0/416 (0.00%)	0/416 (0.00%)	0/415 (0.00%)	1/418 (0.24%)	0/127 (0.00%)	0/122 (0.00%)	0/122 (0.00%)
Pancreatitis acute † [1]							
# participants affected / at risk	1/416 (0.24%)	0/416 (0.00%)	1/415 (0.24%)	0/418 (0.00%)	0/127 (0.00%)	0/122 (0.00%)	0/122 (0.00%)

Small intestinal obstruction † [1]							
# participants affected / at risk	**0/416 (0.00%)**	**0/416 (0.00%)**	**0/415 (0.00%)**	**0/418 (0.00%)**	**1/127 (0.79%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Volvulus † [1]							
# participants affected / at risk	**0/416 (0.00%)**	**0/416 (0.00%)**	**0/415 (0.00%)**	**0/418 (0.00%)**	**0/127 (0.00%)**	**2/122 (1.64%)**	**0/122 (0.00%)**
Vomiting † [1]							
# participants affected / at risk	**0/416 (0.00%)**	**0/416 (0.00%)**	**1/415 (0.24%)**	**1/418 (0.24%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
General disorders							
Chest discomfort † [1]							
# participants affected / at risk	**0/416 (0.00%)**	**0/416 (0.00%)**	**0/415 (0.00%)**	**1/418 (0.24%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Chills † [1]							
# participants affected / at risk	**0/416 (0.00%)**	**0/416 (0.00%)**	**0/415 (0.00%)**	**1/418 (0.24%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Fatigue † [1]							
# participants affected / at risk	**0/416 (0.00%)**	**0/416 (0.00%)**	**1/415 (0.24%)**	**0/418 (0.00%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Non-cardiac chest pain † [1]							
# participants affected / at risk	**1/416 (0.24%)**	**0/416 (0.00%)**	**0/415 (0.00%)**	**1/418 (0.24%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Pain † [1]							

# participants affected / at risk	0/416 (0.00%)	0/416 (0.00%)	1/415 (0.24%)	0/418 (0.00%)	0/127 (0.00%)	0/122 (0.00%)	0/122 (0.00%)
Sudden death † [1]							
# participants affected / at risk	1/416 (0.24%)	0/416 (0.00%)	0/415 (0.00%)	0/418 (0.00%)	0/127 (0.00%)	0/122 (0.00%)	0/122 (0.00%)
Hepatobiliary disorders							
Bile duct stone † [1]							
# participants affected / at risk	0/416 (0.00%)	0/416 (0.00%)	0/415 (0.00%)	1/418 (0.24%)	0/127 (0.00%)	0/122 (0.00%)	0/122 (0.00%)
Cholelithiasis † [1]							
# participants affected / at risk	0/416 (0.00%)	1/416 (0.24%)	0/415 (0.00%)	0/418 (0.00%)	0/127 (0.00%)	0/122 (0.00%)	0/122 (0.00%)
Immune system disorders							
Drug hypersensitivity † [1]							
# participants affected / at risk	0/416 (0.00%)	0/416 (0.00%)	0/415 (0.00%)	0/418 (0.00%)	0/127 (0.00%)	1/122 (0.82%)	0/122 (0.00%)
Infections and infestations							
Bronchitis † [1]							
# participants affected / at risk	0/416 (0.00%)	2/416 (0.48%)	1/415 (0.24%)	3/418 (0.72%)	1/127 (0.79%)	0/122 (0.00%)	0/122 (0.00%)
Bronchopneumonia † [1]							

# participants affected / at risk	0/416 (0.00%)	0/416 (0.00%)	1/415 (0.24%)	0/418 (0.00%)	0/127 (0.00%)	0/122 (0.00%)	0/122 (0.00%)
Cellulitis † [1]							
# participants affected / at risk	0/416 (0.00%)	0/416 (0.00%)	0/415 (0.00%)	1/418 (0.24%)	0/127 (0.00%)	0/122 (0.00%)	0/122 (0.00%)
Clostridium difficile colitis † [1]							
# participants affected / at risk	0/416 (0.00%)	0/416 (0.00%)	0/415 (0.00%)	1/418 (0.24%)	0/127 (0.00%)	0/122 (0.00%)	0/122 (0.00%)
Diverticulitis † [1]							
# participants affected / at risk	0/416 (0.00%)	0/416 (0.00%)	0/415 (0.00%)	1/418 (0.24%)	0/127 (0.00%)	0/122 (0.00%)	0/122 (0.00%)
Herpes zoster oticus † [1]							
# participants affected / at risk	0/416 (0.00%)	0/416 (0.00%)	0/415 (0.00%)	0/418 (0.00%)	0/127 (0.00%)	0/122 (0.00%)	1/122 (0.82%)
Infection † [1]							
# participants affected / at risk	1/416 (0.24%)	0/416 (0.00%)	0/415 (0.00%)	0/418 (0.00%)	0/127 (0.00%)	0/122 (0.00%)	0/122 (0.00%)
Lobar pneumonia † [1]							
# participants affected / at risk	1/416 (0.24%)	0/416 (0.00%)	0/415 (0.00%)	1/418 (0.24%)	0/127 (0.00%)	0/122 (0.00%)	0/122 (0.00%)
Localised infection † [1]							
# participants							

affected / at risk	0/416 (0.00%)	0/416 (0.00%)	0/415 (0.00%)	0/418 (0.00%)	0/127 (0.00%)	1/122 (0.82%)	0/122 (0.00%)
Lower respiratory tract infection † [1]							
# participants affected / at risk	2/416 (0.48%)	0/416 (0.00%)	0/415 (0.00%)	1/418 (0.24%)	0/127 (0.00%)	0/122 (0.00%)	0/122 (0.00%)
Mycobacterial infection † [1]							
# participants affected / at risk	0/416 (0.00%)	0/416 (0.00%)	0/415 (0.00%)	1/418 (0.24%)	0/127 (0.00%)	0/122 (0.00%)	0/122 (0.00%)
Osteomyelitis † [1]							
# participants affected / at risk	0/416 (0.00%)	0/416 (0.00%)	1/415 (0.24%)	0/418 (0.00%)	0/127 (0.00%)	0/122 (0.00%)	0/122 (0.00%)
Pneumonia † [1]							
# participants affected / at risk	2/416 (0.48%)	3/416 (0.72%)	4/415 (0.96%)	4/418 (0.96%)	1/127 (0.79%)	0/122 (0.00%)	0/122 (0.00%)
Pneumonia bacterial † [1]							
# participants affected / at risk	0/416 (0.00%)	0/416 (0.00%)	1/415 (0.24%)	0/418 (0.00%)	0/127 (0.00%)	0/122 (0.00%)	0/122 (0.00%)
Pneumonia streptococcal † [1]							
# participants affected / at risk	0/416 (0.00%)	1/416 (0.24%)	0/415 (0.00%)	0/418 (0.00%)	0/127 (0.00%)	0/122 (0.00%)	0/122 (0.00%)
Sinusitis † [1]							
# participants affected / at risk	1/416 (0.24%)	0/416 (0.00%)	0/415 (0.00%)	0/418 (0.00%)	0/127 (0.00%)	0/122 (0.00%)	0/122 (0.00%)

Staphylococcal infection † [1]							
# participants affected / at risk	**0/416 (0.00%)**	**0/416 (0.00%)**	**1/415 (0.24%)**	**0/418 (0.00%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Upper respiratory tract infection † [1]							
# participants affected / at risk	**1/416 (0.24%)**	**0/416 (0.00%)**	**0/415 (0.00%)**	**0/418 (0.00%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Upper respiratory tract infection bacterial † [1]							
# participants affected / at risk	**0/416 (0.00%)**	**0/416 (0.00%)**	**0/415 (0.00%)**	**2/418 (0.48%)**	**1/127 (0.79%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Injury, poisoning and procedural complications							
Accidental overdose † [1]							
# participants affected / at risk	**1/416 (0.24%)**	**0/416 (0.00%)**	**0/415 (0.00%)**	**0/418 (0.00%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Chest injury † [1]							
# participants affected / at risk	**0/416 (0.00%)**	**1/416 (0.24%)**	**0/415 (0.00%)**	**0/418 (0.00%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Contusion † [1]							
# participants affected / at risk	**0/416 (0.00%)**	**0/416 (0.00%)**	**1/415 (0.24%)**	**0/418 (0.00%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**0/122 (0.00%)**

Device failure † [1]							
# participants affected / at risk	**1/416 (0.24%)**	**0/416 (0.00%)**	**0/415 (0.00%)**	**0/418 (0.00%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Ear injury † [1]							
# participants affected / at risk	**0/416 (0.00%)**	**0/416 (0.00%)**	**1/415 (0.24%)**	**0/418 (0.00%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Excoriation † [1]							
# participants affected / at risk	**0/416 (0.00%)**	**0/416 (0.00%)**	**1/415 (0.24%)**	**0/418 (0.00%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Fall † [1]							
# participants affected / at risk	**1/416 (0.24%)**	**0/416 (0.00%)**	**0/415 (0.00%)**	**1/418 (0.24%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Foot fracture † [1]							
# participants affected / at risk	**0/416 (0.00%)**	**1/416 (0.24%)**	**0/415 (0.00%)**	**0/418 (0.00%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Hand fracture † [1]							
# participants affected / at risk	**0/416 (0.00%)**	**0/416 (0.00%)**	**0/415 (0.00%)**	**1/418 (0.24%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Hip fracture † [1]							
# participants affected / at risk	**0/416 (0.00%)**	**1/416 (0.24%)**	**0/415 (0.00%)**	**1/418 (0.24%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Rib fracture † [1]							
# participants affected / at risk	**0/416 (0.00%)**	**1/416 (0.24%)**	**1/415 (0.24%)**	**0/418 (0.00%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**0/122 (0.00%)**

Road traffic accident † 1							
# participants affected / at risk	**0/416 (0.00%)**	**1/416 (0.24%)**	**2/415 (0.48%)**	**0/418 (0.00%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Skull fractured base † 1							
# participants affected / at risk	**0/416 (0.00%)**	**0/416 (0.00%)**	**1/415 (0.24%)**	**0/418 (0.00%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Spinal fracture † 1							
# participants affected / at risk	**0/416 (0.00%)**	**0/416 (0.00%)**	**1/415 (0.24%)**	**0/418 (0.00%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Investigations							
Blood potassium increased † 1							
# participants affected / at risk	**1/416 (0.24%)**	**0/416 (0.00%)**	**0/415 (0.00%)**	**0/418 (0.00%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Blood urine present † 1							
# participants affected / at risk	**0/416 (0.00%)**	**0/416 (0.00%)**	**1/415 (0.24%)**	**1/418 (0.24%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Glasgow coma scale abnormal † 1							
# participants affected / at risk	**0/416 (0.00%)**	**0/416 (0.00%)**	**1/415 (0.24%)**	**0/418 (0.00%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Metabolism and nutrition disorders							

Dehydration † [1]							
# participants affected / at risk	**1/416 (0.24%)**	**0/416 (0.00%)**	**0/415 (0.00%)**	**1/418 (0.24%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Musculoskeletal and connective tissue disorders							
Arthritis † [1]							
# participants affected / at risk	**0/416 (0.00%)**	**0/416 (0.00%)**	**0/415 (0.00%)**	**0/418 (0.00%)**	**0/127 (0.00%)**	**1/122 (0.82%)**	**0/122 (0.00%)**
Intervertebral disc protrusion † [1]							
# participants affected / at risk	**0/416 (0.00%)**	**0/416 (0.00%)**	**0/415 (0.00%)**	**0/418 (0.00%)**	**1/127 (0.79%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Joint swelling † [1]							
# participants affected / at risk	**0/416 (0.00%)**	**0/416 (0.00%)**	**1/415 (0.24%)**	**0/418 (0.00%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Muscle spasms † [1]							
# participants affected / at risk	**0/416 (0.00%)**	**0/416 (0.00%)**	**1/415 (0.24%)**	**0/418 (0.00%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**1/122 (0.82%)**
Osteoarthritis † [1]							
# participants affected / at risk	**0/416 (0.00%)**	**0/416 (0.00%)**	**1/415 (0.24%)**	**0/418 (0.00%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Osteonecrosis † [1]							
# participants affected / at risk	**0/416 (0.00%)**	**1/416 (0.24%)**	**0/415 (0.00%)**	**0/418 (0.00%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**0/122 (0.00%)**

Pain in extremity † [1]							
# participants affected / at risk	**0/416 (0.00%)**	**0/416 (0.00%)**	**0/415 (0.00%)**	**1/418 (0.24%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Rotator cuff syndrome † [1]							
# participants affected / at risk	**1/416 (0.24%)**	**0/416 (0.00%)**	**0/415 (0.00%)**	**0/418 (0.00%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Acute leukaemia † [1]							
# participants affected / at risk	**0/416 (0.00%)**	**0/416 (0.00%)**	**0/415 (0.00%)**	**1/418 (0.24%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Anaplastic large cell lymphoma T- and null-cell types † [1]							
# participants affected / at risk	**0/416 (0.00%)**	**1/416 (0.24%)**	**0/415 (0.00%)**	**0/418 (0.00%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Benign lung neoplasm † [1]							
# participants affected / at risk	**0/416 (0.00%)**	**0/416 (0.00%)**	**1/415 (0.24%)**	**0/418 (0.00%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Breast cancer † [1]							
# participants affected / at risk	**0/416 (0.00%)**	**0/416 (0.00%)**	**0/415 (0.00%)**	**1/418 (0.24%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Laryngeal cancer † [1]							

# participants affected / at risk	0/416 (0.00%)	1/416 (0.24%)	0/415 (0.00%)	0/418 (0.00%)	0/127 (0.00%)	0/122 (0.00%)	0/122 (0.00%)
Lipoma † [1]							
# participants affected / at risk	0/416 (0.00%)	1/416 (0.24%)	0/415 (0.00%)	0/418 (0.00%)	0/127 (0.00%)	0/122 (0.00%)	0/122 (0.00%)
Lung adenocarcinoma † [1]							
# participants affected / at risk	0/416 (0.00%)	0/416 (0.00%)	1/415 (0.24%)	2/418 (0.48%)	0/127 (0.00%)	0/122 (0.00%)	0/122 (0.00%)
Lung neoplasm malignant † [1]							
# participants affected / at risk	0/416 (0.00%)	1/416 (0.24%)	0/415 (0.00%)	0/418 (0.00%)	0/127 (0.00%)	1/122 (0.82%)	0/122 (0.00%)
Oesophageal carcinoma † [1]							
# participants affected / at risk	0/416 (0.00%)	0/416 (0.00%)	0/415 (0.00%)	1/418 (0.24%)	0/127 (0.00%)	0/122 (0.00%)	0/122 (0.00%)
Prostate cancer † [1]							
# participants affected / at risk	0/416 (0.00%)	1/416 (0.24%)	0/415 (0.00%)	0/418 (0.00%)	0/127 (0.00%)	0/122 (0.00%)	0/122 (0.00%)
Renal cancer † [1]							
# participants affected / at risk	0/416 (0.00%)	0/416 (0.00%)	1/415 (0.24%)	0/418 (0.00%)	0/127 (0.00%)	0/122 (0.00%)	0/122 (0.00%)
Squamous cell carcinoma † [1]							
# participants							

affected / at risk	0/416 (0.00%)	1/416 (0.24%)	0/415 (0.00%)	0/418 (0.00%)	0/127 (0.00%)	0/122 (0.00%)	0/122 (0.00%)
Thyroid neoplasm † [1]							
# participants affected / at risk	1/416 (0.24%)	0/416 (0.00%)	0/415 (0.00%)	0/418 (0.00%)	0/127 (0.00%)	0/122 (0.00%)	0/122 (0.00%)
Nervous system disorders							
Carotid artery occlusion † [1]							
# participants affected / at risk	0/416 (0.00%)	1/416 (0.24%)	0/415 (0.00%)	0/418 (0.00%)	0/127 (0.00%)	0/122 (0.00%)	0/122 (0.00%)
Cerebellar infarction † [1]							
# participants affected / at risk	0/416 (0.00%)	0/416 (0.00%)	0/415 (0.00%)	1/418 (0.24%)	0/127 (0.00%)	0/122 (0.00%)	0/122 (0.00%)
Cerebral haematoma † [1]							
# participants affected / at risk	0/416 (0.00%)	0/416 (0.00%)	1/415 (0.24%)	0/418 (0.00%)	0/127 (0.00%)	0/122 (0.00%)	0/122 (0.00%)
Cerebral haemorrhage † [1]							
# participants affected / at risk	0/416 (0.00%)	1/416 (0.24%)	0/415 (0.00%)	0/418 (0.00%)	0/127 (0.00%)	0/122 (0.00%)	0/122 (0.00%)
Dizziness † [1]							
# participants affected / at risk	0/416 (0.00%)	0/416 (0.00%)	0/415 (0.00%)	1/418 (0.24%)	0/127 (0.00%)	0/122 (0.00%)	0/122 (0.00%)

Loss of consciousness † 1							
# participants affected / at risk	**0/416 (0.00%)**	**0/416 (0.00%)**	**1/415 (0.24%)**	**1/418 (0.24%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Presyncope † 1							
# participants affected / at risk	**0/416 (0.00%)**	**1/416 (0.24%)**	**0/415 (0.00%)**	**0/418 (0.00%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Sciatica † 1							
# participants affected / at risk	**0/416 (0.00%)**	**0/416 (0.00%)**	**0/415 (0.00%)**	**0/418 (0.00%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**1/122 (0.82%)**
Syncope † 1							
# participants affected / at risk	**1/416 (0.24%)**	**2/416 (0.48%)**	**1/415 (0.24%)**	**0/418 (0.00%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Syncope vasovagal † 1							
# participants affected / at risk	**0/416 (0.00%)**	**0/416 (0.00%)**	**1/415 (0.24%)**	**0/418 (0.00%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Transient ischaemic attack † 1							
# participants affected / at risk	**0/416 (0.00%)**	**0/416 (0.00%)**	**0/415 (0.00%)**	**0/418 (0.00%)**	**1/127 (0.79%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Visual midline shift syndrome † 1							
# participants affected / at risk	**0/416 (0.00%)**	**0/416 (0.00%)**	**1/415 (0.24%)**	**0/418 (0.00%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**0/122 (0.00%)**

Psychiatric disorders							
Disorientation † [1]							
# participants affected / at risk	**1/416 (0.24%)**	**0/416 (0.00%)**	**0/415 (0.00%)**	**0/418 (0.00%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Psychiatric decompensation † [1]							
# participants affected / at risk	**0/416 (0.00%)**	**0/416 (0.00%)**	**0/415 (0.00%)**	**0/418 (0.00%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**1/122 (0.82%)**
Suicide attempt † [1]							
# participants affected / at risk	**0/416 (0.00%)**	**0/416 (0.00%)**	**0/415 (0.00%)**	**1/418 (0.24%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Renal and urinary disorders							
Calculus ureteric † [1]							
# participants affected / at risk	**0/416 (0.00%)**	**1/416 (0.24%)**	**0/415 (0.00%)**	**0/418 (0.00%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Haematuria † [1]							
# participants affected / at risk	**0/416 (0.00%)**	**1/416 (0.24%)**	**0/415 (0.00%)**	**0/418 (0.00%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Reproductive system and breast disorders							
Benign prostatic hyperplasia † [1]							
# participants affected / at risk	**1/416 (0.24%)**	**0/416 (0.00%)**	**0/415 (0.00%)**	**0/418 (0.00%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**0/122 (0.00%)**

Pelvic peritoneal adhesions † [1]							
# participants affected / at risk	**0/416 (0.00%)**	**0/416 (0.00%)**	**0/415 (0.00%)**	**0/418 (0.00%)**	**0/127 (0.00%)**	**1/122 (0.82%)**	**0/122 (0.00%)**
Respiratory, thoracic and mediastinal disorders							
Chronic obstructive pulmonary disease † [1]							
# participants affected / at risk	**11/416 (2.64%)**	**7/416 (1.68%)**	**7/415 (1.69%)**	**10/418 (2.39%)**	**3/127 (2.36%)**	**1/122 (0.82%)**	**0/122 (0.00%)**
Cough † [1]							
# participants affected / at risk	**0/416 (0.00%)**	**1/416 (0.24%)**	**0/415 (0.00%)**	**1/418 (0.24%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Dyspnoea † [1]							
# participants affected / at risk	**0/416 (0.00%)**	**2/416 (0.48%)**	**0/415 (0.00%)**	**3/418 (0.72%)**	**1/127 (0.79%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Increased upper airway secretion † [1]							
# participants affected / at risk	**0/416 (0.00%)**	**1/416 (0.24%)**	**0/415 (0.00%)**	**0/418 (0.00%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Pleural effusion † [1]							
# participants affected / at risk	**0/416 (0.00%)**	**0/416 (0.00%)**	**0/415 (0.00%)**	**1/418 (0.24%)**	**0/127 (0.00%)**	**0/122 (0.00%)**	**0/122 (0.00%)**
Pneumothorax † [1]							

# participants affected / at risk	0/416 (0.00%)	0/416 (0.00%)	1/415 (0.24%)	0/418 (0.00%)	0/127 (0.00%)	0/122 (0.00%)	0/122 (0.00%)
Respiratory failure † [1]							
# participants affected / at risk	0/416 (0.00%)	0/416 (0.00%)	1/415 (0.24%)	0/418 (0.00%)	0/127 (0.00%)	0/122 (0.00%)	0/122 (0.00%)
Wheezing † [1]							
# participants affected / at risk	0/416 (0.00%)	0/416 (0.00%)	0/415 (0.00%)	1/418 (0.24%)	0/127 (0.00%)	0/122 (0.00%)	0/122 (0.00%)
Skin and subcutaneous tissue disorders							
Hyperhidrosis † [1]							
# participants affected / at risk	0/416 (0.00%)	0/416 (0.00%)	0/415 (0.00%)	1/418 (0.24%)	0/127 (0.00%)	0/122 (0.00%)	0/122 (0.00%)
Surgical and medical procedures							
Cardioversion † [1]							
# participants affected / at risk	0/416 (0.00%)	0/416 (0.00%)	1/415 (0.24%)	0/418 (0.00%)	0/127 (0.00%)	0/122 (0.00%)	0/122 (0.00%)
Vascular disorders							
Aortic aneurysm † [1]							
# participants affected / at risk	1/416 (0.24%)	0/416 (0.00%)	1/415 (0.24%)	0/418 (0.00%)	0/127 (0.00%)	0/122 (0.00%)	0/122 (0.00%)
Arteriosclerosis † [1]							

# participants affected / at risk	0/416 (0.00%)	0/416 (0.00%)	1/415 (0.24%)	0/418 (0.00%)	0/127 (0.00%)	0/122 (0.00%)	0/122 (0.00%)
Deep vein thrombosis † [1]							
# participants affected / at risk	0/416 (0.00%)	0/416 (0.00%)	1/415 (0.24%)	0/418 (0.00%)	0/127 (0.00%)	0/122 (0.00%)	0/122 (0.00%)
Haematoma † [1]							
# participants affected / at risk	0/416 (0.00%)	0/416 (0.00%)	1/415 (0.24%)	0/418 (0.00%)	0/127 (0.00%)	0/122 (0.00%)	0/122 (0.00%)
Intermittent claudication † [1]							
# participants affected / at risk	0/416 (0.00%)	1/416 (0.24%)	0/415 (0.00%)	0/418 (0.00%)	0/127 (0.00%)	0/122 (0.00%)	0/122 (0.00%)
Orthostatic hypotension † [1]							
# participants affected / at risk	1/416 (0.24%)	0/416 (0.00%)	0/415 (0.00%)	0/418 (0.00%)	0/127 (0.00%)	0/122 (0.00%)	0/122 (0.00%)
Peripheral arterial occlusive disease † [1]							
# participants affected / at risk	0/416 (0.00%)	0/416 (0.00%)	1/415 (0.24%)	0/418 (0.00%)	0/127 (0.00%)	0/122 (0.00%)	0/122 (0.00%)
Peripheral vascular disorder † [1]							
# participants affected / at risk	1/416 (0.24%)	0/416 (0.00%)	0/415 (0.00%)	0/418 (0.00%)	0/127 (0.00%)	0/122 (0.00%)	0/122 (0.00%)

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	Safety Population including all participants who received at least one dose of study drug.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Indacaterol 150 µg (Continued Into Stage 2)	In the morning, Indacaterol 150 µg once daily orally inhaled via a single dose dry powder inhaler (SDDPI) + Placebo to Indacaterol delivered via SDDPI + Placebo to Formoterol delivered via Aerolizer. In the evening, Placebo to Formoterol delivered via Aerolizer. Participated in the 2 week Stage 1 and continued treatment up to 26 weeks in Stage 2. Placebo to Formoterol inhalation in the morning and in the evening was discontinued after Stage 1. Daily Inhaled Corticosteroid (ICS) monotherapy (if applicable) was to remain stable and Salbutamol/albuterol was available for rescue use throughout study.
Indacaterol 300 µg (Continued Into Stage 2)	In the morning, Indacaterol 300 µg once daily orally inhaled via a SDDPI + Placebo to Indacaterol delivered via SDDPI + Placebo to Formoterol delivered via Aerolizer. In evening, Placebo to Formoterol delivered via Aerolizer. Participated in the 2 week Stage 1 and continued treatment up to 26 weeks in Stage 2. Placebo to Formoterol inhalation in the morning and in the evening was discontinued after Stage 1. Daily ICS monotherapy (if applicable) was to remain stable and Salbutamol/albuterol was available for rescue use throughout study.

Tiotropium 18 µg (Continued Into Stage 2)	Tiotropium 18 µg dry powder capsules delivered (open label) via manufacturer's proprietary SDDPI, (Handihaler®). Participated in the 2 week Stage 1 and continued treatment up to 26 weeks in Stage 2. Daily ICS monotherapy (if applicable) was to remain stable and Salbutamol/albuterol was available for rescue use throughout study.
Placebo (Continued Into Stage 2)	In the morning, Placebo to Indacaterol delivered via two SDDPI devices + Placebo to Formoterol delivered via Aerolizer. In the evening, Placebo to Formoterol delivered via Aerolizer. Participated in the 2 week Stage 1 and continued treatment up to 26 weeks in Stage 2. Placebo to Formoterol inhalation in the morning and in the evening was discontinued after Stage 1. Daily ICS monotherapy (if applicable) was to remain stable and Salbutamol/albuterol was available for rescue use throughout study.
Indacaterol 75 µg (Not Continued Into Stage 2)	In the morning, Indacaterol 75 µg once daily orally inhaled via a SDDPI + Placebo to Indacaterol delivered via SDDPI + Placebo to Formoterol delivered via Aerolizer. In the evening, Placebo to Formoterol delivered via Aerolizer. Participated in the 2 week Stage 1 but did not continue to Stage 2. Daily ICS monotherapy (if applicable) was to remain stable and Salbutamol/albuterol was available for rescue use throughout study.
Indacaterol 600 µg (Not Continued Into Stage 2)	In the morning, 2 capsules of Indacaterol 300 µg once daily orally inhaled via two SDDPI devices + Placebo to Formoterol delivered via Aerolizer. In the evening, Placebo to Formoterol delivered via Aerolizer. Participated in the 2 week Stage 1 but did not continue to Stage 2. Daily ICS monotherapy (if applicable) was to remain stable and Salbutamol/albuterol was available for rescue use throughout study.
Formoterol 12 µg (Not Continued Into Stage 2)	In the morning, Placebo to Indacaterol delivered via two SDDPI devices + Formoterol 12 µg delivered via Aerolizer. In evening, Formoterol 12 µg delivered via Aerolizer. Participated in the 2 week Stage 1 but did not continue to Stage 2. Daily ICS monotherapy (if applicable) was to remain stable and Salbutamol/albuterol was available for rescue use throughout study.

Other Adverse Events

	Indacaterol 150 µg (Continued Into Stage 2)	Indacaterol 300 µg (Continued Into Stage 2)	Tiotropium 18 µg (Continued Into Stage 2)	Placebo (Continued Into Stage 2)	Indacaterol 75 µg (Not Continued Into Stage 2)	Indacaterol 600 µg (Not Continued Into Stage 2)	Formoterol 12 µg (Not Continued Into Stage 2)
Total, other (not including serious) adverse events							
# participants affected / at risk	159/416 (38.22%)	159/416 (38.22%)	156/415 (37.59%)	155/418 (37.08%)	39/127 (30.71%)	44/122 (36.07%)	31/122 (25.41%)
Infections and infestations							
Bronchitis † [1]							
# participants affected / at risk	7/416 (1.68%)	17/416 (4.09%)	13/415 (3.13%)	24/418 (5.74%)	2/127 (1.57%)	3/122 (2.46%)	3/122 (2.46%)
Nasopharyngitis † [1]							
# participants affected / at risk	33/416 (7.93%)	39/416 (9.38%)	36/415 (8.67%)	36/418 (8.61%)	7/127 (5.51%)	8/122 (6.56%)	4/122 (3.28%)
Upper respiratory tract infection † [1]							
# participants affected / at risk	34/416 (8.17%)	27/416 (6.49%)	31/415 (7.47%)	31/418 (7.42%)	10/127 (7.87%)	11/122 (9.02%)	3/122 (2.46%)
Musculoskeletal and connective tissue disorders							
Muscle spasms							

† [1]							
# participants affected / at risk	13/416 (3.13%)	13/416 (3.13%)	6/415 (1.45%)	4/418 (0.96%)	1/127 (0.79%)	9/122 (7.38%)	4/122 (3.28%)
Nervous system disorders							
Headache † [1]							
# participants affected / at risk	28/416 (6.73%)	18/416 (4.33%)	19/415 (4.58%)	14/418 (3.35%)	10/127 (7.87%)	3/122 (2.46%)	6/122 (4.92%)
Respiratory, thoracic and mediastinal disorders							
Chronic obstructive pulmonary disease † [1]							
# participants affected / at risk	67/416 (16.11%)	72/416 (17.31%)	75/415 (18.07%)	86/418 (20.57%)	11/127 (8.66%)	19/122 (15.57%)	16/122 (13.11%
Cough † [1]							
# participants affected / at risk	30/416 (7.21%)	30/416 (7.21%)	26/415 (6.27%)	27/418 (6.46%)	7/127 (5.51%)	6/122 (4.92%)	4/122 (3.28%)

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.
There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.
The agreement is: ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed. ☑ **Restriction Description:** The terms and conditions of Novartis' agreements with its investigators may vary. However, Novartis does not prohibit any investigator from publishing. Any publications from a single-site are postponed until the publication of the pooled data (i.e., data from all sites) in the clinical trial.

Results Point of Contact:

Name/Title: Study Director
Organization: Novartis Pharmaceuticals

phone: 862-778-8300

No publications provided by Novartis

Publications automatically indexed to this study:

Jones PW, Donohue JF, Nedelman J, Pascoe S, Pinault G, Lassen C. Correlating changes in lung function with patient outcomes in chronic obstructive pulmonary disease: a pooled analysis. Respir Res. 2011 Dec 29;12:161. doi: 10.1186/1465-9921-12-161.

Yelensky R, Li Y, Lewitzky S, Leroy E, Hurwitz C, Rodman D, Trifilieff A, Paulding CA. A pharmacogenetic study of ADRB2 polymorphisms and indacaterol response in COPD patients. Pharmacogenomics J. 2012 Dec;12(6):484-8. doi: 10.1038/tpj.2011.54. Epub 2011 Dec 13.

Jones PW, Mahler DA, Gale R, Owen R, Kramer B. Profiling the effects of indacaterol on dyspnoea and health status in patients with COPD. Respir Med. 2011 Jun;105(6):892-9. doi: 10.1016/j.rmed.2011.02.013. Epub 2011 Mar 11.

Worth H, Chung KF, Felser JM, Hu H, Rueegg P. Cardio- and cerebrovascular safety of indacaterol vs formoterol, salmeterol, tiotropium and placebo in COPD. Respir Med. 2011 Apr;105(4):571-9. doi: 10.1016/j.rmed.2010.11.027. Epub 2011 Jan 11.

Donohue JF, Fogarty C, Lötvall J, Mahler DA, Worth H, Yorgancioglu A, Iqbal A, Swales J, Owen R, Higgins M, Kramer B; INHANCE Study Investigators. Once-daily bronchodilators for chronic obstructive pulmonary disease: indacaterol versus tiotropium. Am J Respir Crit Care Med. 2010 Jul 15;182(2):155-62. doi: 10.1164/rccm.200910-1500OC. Epub 2010 May 12.

Responsible Party:	external affairs, Novartis
ClinicalTrials.gov Identifier:	NCT00463567 History of Changes
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Health Authority:	Argentina: Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica Germany: Federal Institute for Drugs and Medical Devices Spain: Spanish Agency of Medicines France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis) Canada: Health Canada Italy: Direzione Generale di Sanità Veterinaria e degli Alimenti Korea: Food and Drug Administration United States: Food and Drug Administration Taiwan: Department of Health India: Institutional Review Board

Sweden: Medical Products Agency
Turkey: Ministry of Health
Venezuela: Intituto Nacional de Higiene Rafael Rangel