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Trial record **1 of 1** for: CQMF149B2201

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A Dose Ranging Trial of 4 Doses of Indacaterol Delivered Via the TWISTHALER® Device in Patients With Chronic Obstructive Pulmonary Disease (COPD)

This study has been completed.

Sponsor:
Novartis

Collaborator:
Schering-Plough

Information provided by (Responsible Party):
Novartis

ClinicalTrials.gov Identifier:
NCT00557466

First received: November 13, 2007
Last updated: December 12, 2012
Last verified: November 2012
History of Changes

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Results First Received: November 12, 2012

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
Condition:	COPD

Interventions:	Drug: indacaterol Drug: formoterol Drug: placebo to indacaterol Drug: placebo to formoterol Drug: short acting β2- agonist

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
No text entered.

Reporting Groups

	Description
Indacaterol 62.5 µg	Indacaterol 62.5 µg delivered by the TWISTHALER® device once a day and placebo to formoterol (placebo AEROLIZER® device) twice a day for 14 days.
Indacaterol 125 µg	Indacaterol 125 µg delivered by the TWISTHALER® device once a day and placebo to formoterol (placebo AEROLIZER® device) twice a day for 14 days.
Indacaterol 250 µg	Indacaterol 250 µg delivered by the TWISTHALER® device once a day and placebo to formoterol (placebo AEROLIZER® device) twice a day for 14 days.
Indacaterol 500 µg	Indacaterol 500 µg delivered by the TWISTHALER® device once a day and placebo to formoterol (placebo AEROLIZER® device) twice a day for 14 days.
Formoterol	Formoterol 12 µg delivered by the AEROLIZER® device twice a day and placebo to indacaterol (placebo TWISTHALER® device) once a day for 14 days.

Placebo	Placebo to indacaterol (placebo TWISTHALER® placebo) once a day and placebo to formoterol (placebo AEROLIZER® device) twice a day for 14 days.

Participant Flow: Overall Study

	Indacaterol 62.5 µg	Indacaterol 125 µg	Indacaterol 250 µg	Indacaterol 500 µg	Formoterol	Placebo
STARTED	98	92	101	96	90	91
Safety Population	98 [1]	92 [1]	101 [1]	96 [1]	90 [1]	91 [1]
Intent to Treat Population	98 [2]	91 [2]	98 [2]	93 [2]	87 [2]	89 [2]
COMPLETED	94	87	95	92	87	85
NOT COMPLETED	4	5	6	4	3	6
Adverse Event	3	1	4	1	2	4
Abnormal laboratory value(s)	1	2	0	0	0	0
Protocol deviation	0	1	0	2	0	0
Subject withdrew consent	0	0	0	0	1	2
Administrative problems	0	1	1	0	0	0
Abnormal test procedure results	0	0	1	0	0	0
Lost to Follow-up	0	0	0	1	0	0

[1] All randomized patients who received at least one dose of the study drug

[2] All randomized patients who had a baseline and at least one post-dose FEV1 measurement

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 62.5 µg	Indacaterol 62.5 µg delivered by the TWISTHALER® device once a day and placebo to formoterol (placebo AEROLIZER® device) twice a day for 14 days.
Indacaterol 125 µg	Indacaterol 125 µg delivered by the TWISTHALER® device once a day and placebo to formoterol (placebo AEROLIZER® device) twice a day for 14 days.
Indacaterol 250 µg	Indacaterol 250 µg delivered by the TWISTHALER® device once a day and placebo to formoterol (placebo AEROLIZER® device) twice a day for 14 days.
Indacaterol 500 µg	Indacaterol 500 µg delivered by the TWISTHALER® device once a day and placebo to formoterol (placebo AEROLIZER® device) twice a day for 14 days.
Formoterol	Formoterol 12 µg delivered by the AEROLIZER® device twice a day and placebo to indacaterol (placebo TWISTHALER® device) once a day for 14 days.
Placebo	Placebo to indacaterol (placebo TWISTHALER® placebo) once a day and placebo to formoterol (placebo AEROLIZER® device) twice a day for 14 days.
Total	Total of all reporting groups

Baseline Measures

	Indacaterol 62.5 µg	Indacaterol 125 µg	Indacaterol 250 µg	Indacaterol 500 µg	Formoterol	Placebo	Total
Number of Participants [units: participants]	98	91	98	93	87	89	556
Age [1] [units: years] Mean (Standard Deviation)	62.1 (7.69)	61.6 (9.51)	61.6 (8.68)	61.9 (8.48)	63.3 (8.36)	62.2 (8.84)	62.1 (8.58)
Gender [units: participants]							
Female	33	23	27	20	29	25	157
Male	65	68	71	73	58	64	399

[1] Total number of baseline participants is based on the Intent to Treat Population

Outcome Measures

Hide All Outcome Measures

1. Primary: The Mean Change From Baseline to 24 Hour Post-dose (Trough) Forced Expiratory Volume in 1 Second (FEV1) [Time Frame: Baseline (prior to first dose) and Day 15 (24 hours after last dose)]

Measure Type	Primary
Measure Title	The Mean Change From Baseline to 24 Hour Post-dose (Trough) Forced Expiratory Volume in 1 Second (FEV1)
Measure Description	FEV1 is the amount of air which can be forcibly exhaled from the lungs in the first second of a forced exhalation. Change from baseline to 24 hour post dose trough FEV1 after 14 days of treatment was analyzed using Analysis of Covariance (ANCOVA) adjusting for treatment and region with baseline FEV1 as a covariate.
Time Frame	Baseline (prior to first dose) and Day 15 (24 hours after last dose)

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.
The intent-to-treat population (ITT) population consisted of all randomized patients who had a baseline and at least one post-dose FEV1 measurement. The analysis only includes patients with non-missing data.

Reporting Groups

	Description
Indacaterol 62.5 µg	Indacaterol 62.5 µg delivered by the TWISTHALER® device once a day and placebo to formoterol (placebo AEROLIZER® device) twice a day for 14 days.
Indacaterol 125 µg	Indacaterol 125 µg delivered by the TWISTHALER® device once a day and placebo to formoterol (placebo AEROLIZER® device) twice a day for 14 days.
Indacaterol 250 µg	Indacaterol 250 µg delivered by the TWISTHALER® device once a day and placebo to formoterol (placebo AEROLIZER® device) twice a day for 14 days.
Indacaterol 500 µg	Indacaterol 500 µg delivered by the TWISTHALER® device once a day and placebo to formoterol (placebo AEROLIZER® device) twice a day for 14 days.
Formoterol	Formoterol 12 µg delivered by the AEROLIZER® device twice a day and placebo to indacaterol (placebo TWISTHALER® device) once a day for 14 days.
Placebo	Placebo to indacaterol (placebo TWISTHALER® placebo) once a day and placebo to formoterol (placebo AEROLIZER® device) twice a day for 14 days.

Measured Values

	Indacaterol 62.5 µg	**Indacaterol 125 µg**	**Indacaterol 250 µg**	**Indacaterol 500 µg**	**Formoterol**	**Placebo**
Number of Participants Analyzed [units: participants]	**92**	**85**	**90**	**89**	**83**	**80**

The Mean Change From Baseline to 24 Hour Post-dose (Trough) Forced Expiratory Volume in 1 Second (FEV1) [units: liters] Least Squares Mean (Standard Error)	**0.051 (0.0207)**	**0.073 (0.0217)**	**0.076 (0.0210)**	**0.121 (0.0211)**	**0.098 (0.0219)**	**0.005 (0.0223)**

No statistical analysis provided for The Mean Change From Baseline to 24 Hour Post-dose (Trough) Forced Expiratory Volume in 1 Second (FEV1)

2. Secondary: Standardized Forced Expiratory Volume in 1 Second (FEV1) Area Under the Curve (AUC) Between Baseline (Predose) and 4 Hours Post-dose [Time Frame: Day 14, pre-dose and at 5, 20, 30 minutes and 1, 2, 3, and 4 hours post-dose.]

Measure Type	Secondary
Measure Title	Standardized Forced Expiratory Volume in 1 Second (FEV1) Area Under the Curve (AUC) Between Baseline (Predose) and 4 Hours Post-dose
Measure Description	FEV1 was measured on Day 14 pre-dose and up to 4 hours post-dose. The Area Under the Curve (AUC) for FEV1 was analyzed using Analysis of Covariance adjusting for treatment and region with baseline FEV1 as a covariate.
Time Frame	Day 14, pre-dose and at 5, 20, 30 minutes and 1, 2, 3, and 4 hours post-dose.
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.
The intent-to-treat population (ITT) population consisted of all randomized patients who had a baseline and at least one post-dose FEV1 measurement. Observed data only.

Reporting Groups

	Description
Indacaterol 62.5 µg	Indacaterol 62.5 µg delivered by the TWISTHALER® device once a day and placebo to formoterol (placebo AEROLIZER® device) twice a day for 14 days.

Indacaterol 125 µg	Indacaterol 125 µg delivered by the TWISTHALER® device once a day and placebo to formoterol (placebo AEROLIZER® device) twice a day for 14 days.
Indacaterol 250 µg	Indacaterol 250 µg delivered by the TWISTHALER® device once a day and placebo to formoterol (placebo AEROLIZER® device) twice a day for 14 days.
Indacaterol 500 µg	Indacaterol 500 µg delivered by the TWISTHALER® device once a day and placebo to formoterol (placebo AEROLIZER® device) twice a day for 14 days.
Formoterol	Formoterol 12 µg delivered by the AEROLIZER® device twice a day and placebo to indacaterol (placebo TWISTHALER® device) once a day for 14 days.
Placebo	Placebo to indacaterol (placebo TWISTHALER® placebo) once a day and placebo to formoterol (placebo AEROLIZER® device) twice a day for 14 days.

Measured Values

	Indacaterol 62.5 µg	Indacaterol 125 µg	Indacaterol 250 µg	Indacaterol 500 µg	Formoterol	Placebo
Number of Participants Analyzed [units: participants]	**93**	**86**	**90**	**89**	**83**	**81**
Standardized Forced Expiratory Volume in 1 Second (FEV1) Area Under the Curve (AUC) Between Baseline (Predose) and 4 Hours Post-dose [units: liters] Least Squares Mean (Standard Error)	**1.407 (0.0193)**	**1.461 (0.0202)**	**1.441 (0.0196)**	**1.500 (0.0198)**	**1.541 (0.0206)**	**1.315 (0.0208)**

No statistical analysis provided for Standardized Forced Expiratory Volume in 1 Second (FEV1) Area Under the Curve (AUC) Between Baseline (Predose) and 4 Hours Post-dose

3. Secondary: The Mean Change From Baseline to 24 Hour Post-dose (Trough) Forced Expiratory Volume in 1 Second (FEV1) on Day 1 [Time Frame: Day 1 Baseline (prior to first dose) and 24 hours post-dose.]

Measure Type	Secondary
Measure Title	The Mean Change From Baseline to 24 Hour Post-dose (Trough) Forced Expiratory Volume in 1 Second (FEV1) on Day 1
Measure Description	FEV1 is the amount of air which can be forcibly exhaled from the lungs in the first second of a forced exhalation. Change from baseline to 24 hour post dose trough FEV1 after 1 day of treatment was analyzed using Analysis of Covariance (ANCOVA) adjusting for treatment and region with baseline FEV1 as a covariate.
Time Frame	Day 1 Baseline (prior to first dose) and 24 hours post-dose.
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.
The intent-to-treat population (ITT) population consisted of all randomized patients who had a baseline and at least one post-dose FEV1 measurement. The analysis only includes patients with non-missing data.

Reporting Groups

	Description
Indacaterol 62.5 µg	Indacaterol 62.5 µg delivered by the TWISTHALER® device once a day and placebo to formoterol (placebo AEROLIZER® device) twice a day for 14 days.
Indacaterol 125 µg	Indacaterol 125 µg delivered by the TWISTHALER® device once a day and placebo to formoterol (placebo AEROLIZER® device) twice a day for 14 days.
Indacaterol 250 µg	Indacaterol 250 µg delivered by the TWISTHALER® device once a day and placebo to formoterol (placebo AEROLIZER® device) twice a day for 14 days.
Indacaterol 500 µg	Indacaterol 500 µg delivered by the TWISTHALER® device once a day and placebo to formoterol (placebo AEROLIZER® device) twice a day for 14 days.
Formoterol	Formoterol 12 µg delivered by the AEROLIZER® device twice a day and placebo to indacaterol (placebo TWISTHALER® device) once a day for 14 days.
Placebo	Placebo to indacaterol (placebo TWISTHALER® placebo) once a day and placebo to formoterol (placebo AEROLIZER®

	device) twice a day for 14 days.

Measured Values

	Indacaterol 62.5 µg	Indacaterol 125 µg	Indacaterol 250 µg	Indacaterol 500 µg	Formoterol	Placebo
Number of Participants Analyzed [units: participants]	**95**	**88**	**96**	**90**	**86**	**87**
The Mean Change From Baseline to 24 Hour Post-dose (Trough) Forced Expiratory Volume in 1 Second (FEV1) on Day 1 [units: liters] Least Squares Mean (Standard Error)	**0.028 (0.0152)**	**0.054 (0.0158)**	**0.060 (0.0151)**	**0.073 (0.0156)**	**0.140 (0.0160)**	**-0.009 (0.0160)**

No statistical analysis provided for The Mean Change From Baseline to 24 Hour Post-dose (Trough) Forced Expiratory Volume in 1 Second (FEV1) on Day 1

4. Secondary: Standardized Forced Expiratory Volume in 1 Second (FEV1) Area Under the Curve (AUC) Between Baseline (Predose) and 4 Hours Post-dose on Day 1 [Time Frame: Day 1; pre-dose and at 5, 20, 30 minutes and 1, 2, 3, and 4 hours post-dose.]

Measure Type	Secondary
Measure Title	Standardized Forced Expiratory Volume in 1 Second (FEV1) Area Under the Curve (AUC) Between Baseline (Predose) and 4 Hours Post-dose on Day 1
Measure Description	FEV1 was measured on Day 1 pre-dose and up to 4 hours post-dose. The Area Under the Curve (AUC) for FEV1 was analyzed using Analysis of Covariance adjusting for treatment and region with baseline FEV1 as a covariate.
Time Frame	Day 1; pre-dose and at 5, 20, 30 minutes and 1, 2, 3, and 4 hours post-dose.
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.
The intent-to-treat population (ITT) population consisted of all randomized patients who had a baseline and at least one post-dose FEV1 measurement. Observed data only.

Reporting Groups

	Description
Indacaterol 62.5 µg	Indacaterol 62.5 µg delivered by the TWISTHALER® device once a day and placebo to formoterol (placebo AEROLIZER® device) twice a day for 14 days.
Indacaterol 125 µg	Indacaterol 125 µg delivered by the TWISTHALER® device once a day and placebo to formoterol (placebo AEROLIZER® device) twice a day for 14 days.
Indacaterol 250 µg	Indacaterol 250 µg delivered by the TWISTHALER® device once a day and placebo to formoterol (placebo AEROLIZER® device) twice a day for 14 days.
Indacaterol 500 µg	Indacaterol 500 µg delivered by the TWISTHALER® device once a day and placebo to formoterol (placebo AEROLIZER® device) twice a day for 14 days.
Formoterol	Formoterol 12 µg delivered by the AEROLIZER® device twice a day and placebo to indacaterol (placebo TWISTHALER® device) once a day for 14 days.
Placebo	Placebo to indacaterol (placebo TWISTHALER® placebo) once a day and placebo to formoterol (placebo AEROLIZER® device) twice a day for 14 days.

Measured Values

	Indacaterol 62.5 µg	**Indacaterol 125 µg**	**Indacaterol 250 µg**	**Indacaterol 500 µg**	**Formoterol**	**Placebo**
Number of Participants Analyzed [units: participants]	**98**	**91**	**97**	**91**	**87**	**87**
Standardized Forced Expiratory Volume in 1 Second (FEV1) Area Under the Curve (AUC) Between Baseline (Predose) and 4 Hours Post-dose on Day 1 [units: liters]	**1.371 (0.0111)**	**1.422 (0.0116)**	**1.427 (0.0112)**	**1.438 (0.0116)**	**1.535 (0.0118)**	**1.321 (0.0118)**

Least Squares Mean (Standard Error)						

No statistical analysis provided for Standardized Forced Expiratory Volume in 1 Second (FEV1) Area Under the Curve (AUC) Between Baseline (Predose) and 4 Hours Post-dose on Day 1

5. Secondary: Time to Peak Forced Expiratory Volume in 1 Second (FEV1) on Day 1 and Day 14 [Time Frame: Day 1 and Day 14 measured pre-dose and up to 4 hours post-dose]

Measure Type	Secondary
Measure Title	Time to Peak Forced Expiratory Volume in 1 Second (FEV1) on Day 1 and Day 14
Measure Description	FEV1 is the amount of air which can be forcibly exhaled from the lungs in the first second of a forced exhalation. Time to peak FEV1 is calculated in minutes from the time of inhalation of study drug to the time of the peak FEV1, which is taken as the maximum FEV1 recorded post-dose.
Time Frame	Day 1 and Day 14 measured pre-dose and up to 4 hours post-dose
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.
The intent-to-treat population (ITT) population consisted of all randomized patients who had a baseline and at least one post-dose FEV1 measurement. The analysis only includes patients with non-missing data, indicated by "N".

Reporting Groups

	Description
Indacaterol 62.5 µg	Indacaterol 62.5 µg delivered by the TWISTHALER® device once a day and placebo to formoterol (placebo AEROLIZER® device) twice a day for 14 days.
Indacaterol 125 µg	Indacaterol 125 µg delivered by the TWISTHALER® device once a day and placebo to formoterol (placebo AEROLIZER® device) twice a day for 14 days.

Indacaterol 250 µg	Indacaterol 250 µg delivered by the TWISTHALER® device once a day and placebo to formoterol (placebo AEROLIZER® device) twice a day for 14 days.
Indacaterol 500 µg	Indacaterol 500 µg delivered by the TWISTHALER® device once a day and placebo to formoterol (placebo AEROLIZER® device) twice a day for 14 days.
Formoterol	Formoterol 12 µg delivered by the AEROLIZER® device twice a day and placebo to indacaterol (placebo TWISTHALER® device) once a day for 14 days.
Placebo	Placebo to indacaterol (placebo TWISTHALER® placebo) once a day and placebo to formoterol (placebo AEROLIZER® device) twice a day for 14 days.

Measured Values

	Indacaterol 62.5 µg	Indacaterol 125 µg	Indacaterol 250 µg	Indacaterol 500 µg	Formoterol	Placebo
Number of Participants Analyzed [units: participants]	**98**	**91**	**98**	**93**	**87**	**89**
Time to Peak Forced Expiratory Volume in 1 Second (FEV1) on Day 1 and Day 14 [units: minutes] Mean (Standard Deviation)						
Day 1 [N=98, 91, 97, 91, 87, 87]	**80.9 (76.01)**	**84.4 (77.74)**	**101.4 (83.44)**	**105.3 (81.85)**	**115.0 (81.59)**	**85.7 (81.44)**
Day 14 [N=93, 86, 90, 89, 83, 82]	**91.3 (81.20)**	**105.6 (82.53)**	**104.7 (75.96)**	**116.4 (85.03)**	**89.1 (72.91)**	**68.0 (70.38)**

No statistical analysis provided for Time to Peak Forced Expiratory Volume in 1 Second (FEV1) on Day 1 and Day 14

6. Secondary: Change From Baseline in Morning and Evening Peak Expiratory Flow [Time Frame: Baseline (recorded during the screening

period) and Days 1-14 (treatment period).]

Measure Type	Secondary
Measure Title	Change From Baseline in Morning and Evening Peak Expiratory Flow
Measure Description	The Peak Expiratory Flow (PEF) rate is the maximal rate that a person can exhale during a short maximal expiratory effort after fully inhaling. Participants measured their PEF using a peak flow meter prior to taking study medication and recorded measurements in a diary every morning and evening during the study. Change from baseline is the difference between the mean baseline PEF recorded during the screening period until the first day of treatment, and the overall mean PEF from Days 1 to 14.
Time Frame	Baseline (recorded during the screening period) and Days 1-14 (treatment period).
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. The analysis only includes patients with non-missing data.

Reporting Groups

	Description
Indacaterol 62.5 µg	Indacaterol 62.5 µg delivered by the TWISTHALER® device once a day and placebo to formoterol (placebo AEROLIZER® device) twice a day for 14 days.
Indacaterol 125 µg	Indacaterol 125 µg delivered by the TWISTHALER® device once a day and placebo to formoterol (placebo AEROLIZER® device) twice a day for 14 days.
Indacaterol 250 µg	Indacaterol 250 µg delivered by the TWISTHALER® device once a day and placebo to formoterol (placebo AEROLIZER® device) twice a day for 14 days.
Indacaterol 500 µg	Indacaterol 500 µg delivered by the TWISTHALER® device once a day and placebo to formoterol (placebo AEROLIZER® device) twice a day for 14 days.
Formoterol	Formoterol 12 µg delivered by the AEROLIZER® device twice a day and placebo to indacaterol (placebo

	TWISTHALER® device) once a day for 14 days.
Placebo	Placebo to indacaterol (placebo TWISTHALER® placebo) once a day and placebo to formoterol (placebo AEROLIZER® device) twice a day for 14 days.

Measured Values

	Indacaterol 62.5 µg	Indacaterol 125 µg	Indacaterol 250 µg	Indacaterol 500 µg	Formoterol	Placebo
Number of Participants Analyzed [units: participants]	**98**	**91**	**98**	**93**	**87**	**89**
Change From Baseline in Morning and Evening Peak Expiratory Flow [units: liters/minute] Mean (Standard Deviation)						
Morning [N=56, 63, 59, 54, 54, 55]	**3.10 (29.709)**	**19.91 (34.060)**	**23.63 (30.707)**	**11.11 (36.787)**	**16.06 (31.544)**	**-4.24 (31.357)**
Evening [N=56, 58, 56, 49, 48, 52]	**-2.72 (28.816)**	**13.42 (30.500)**	**19.00 (24.004)**	**5.92 (43.490)**	**14.97 (40.355)**	**-2.75 (35.034)**

No statistical analysis provided for Change From Baseline in Morning and Evening Peak Expiratory Flow

7. Secondary: Number of Participants Using Rescue Medication [Time Frame: Over 14 days]

Measure Type	Secondary
Measure Title	Number of Participants Using Rescue Medication
Measure Description	Participants recorded the use of rescue medications (salbutamol/albuterol) for treatment of asthma symptoms twice a day in a diary during the 14 days of the treatment period.
Time Frame	Over 14 days

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

Reporting Groups

	Description
Indacaterol 62.5 µg	Indacaterol 62.5 µg delivered by the TWISTHALER® device once a day and placebo to formoterol (placebo AEROLIZER® device) twice a day for 14 days.
Indacaterol 125 µg	Indacaterol 125 µg delivered by the TWISTHALER® device once a day and placebo to formoterol (placebo AEROLIZER® device) twice a day for 14 days.
Indacaterol 250 µg	Indacaterol 250 µg delivered by the TWISTHALER® device once a day and placebo to formoterol (placebo AEROLIZER® device) twice a day for 14 days.
Indacaterol 500 µg	Indacaterol 500 µg delivered by the TWISTHALER® device once a day and placebo to formoterol (placebo AEROLIZER® device) twice a day for 14 days.
Formoterol	Formoterol 12 µg delivered by the AEROLIZER® device twice a day and placebo to indacaterol (placebo TWISTHALER® device) once a day for 14 days.
Placebo	Placebo to indacaterol (placebo TWISTHALER® placebo) once a day and placebo to formoterol (placebo AEROLIZER® device) twice a day for 14 days.

Measured Values

	Indacaterol 62.5 µg	**Indacaterol 125 µg**	**Indacaterol 250 µg**	**Indacaterol 500 µg**	**Formoterol**	**Placebo**
Number of Participants Analyzed [units: participants]	**98**	**91**	**98**	**93**	**87**	**89**
Number of Participants Using Rescue						

Medication [units: participants]						
Day	74	61	73	65	65	70
Night	72	60	67	59	67	72

No statistical analysis provided for Number of Participants Using Rescue Medication

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Reporting Groups

	Description
Indacaterol 62.5 µg	Indacaterol 62.5 µg delivered by the TWISTHALER® device once a day and placebo to formoterol (placebo AEROLIZER® device) twice a day for 14 days.
Indacaterol 125 µg	Indacaterol 125 µg delivered by the TWISTHALER® device once a day and placebo to formoterol (placebo AEROLIZER® device) twice a day for 14 days.
Indacaterol 250 µg	Indacaterol 250 µg delivered by the TWISTHALER® device once a day and placebo to formoterol (placebo AEROLIZER® device) twice a day for 14 days.
Indacaterol 500 µg	Indacaterol 500 µg delivered by the TWISTHALER® device once a day and placebo to formoterol (placebo AEROLIZER® device) twice a day for 14 days.
Formoterol	Formoterol 12 µg delivered by the AEROLIZER® device twice a day and placebo to indacaterol (placebo TWISTHALER® device) once a day for 14 days.
Placebo	Placebo to indacaterol (placebo TWISTHALER® placebo) once a day and placebo to formoterol (placebo AEROLIZER® device) twice a day for 14 days.

Serious Adverse Events

	Indacaterol 62.5 µg	Indacaterol 125 µg	Indacaterol 250 µg	Indacaterol 500 µg	Formoterol	Placebo
Total, serious adverse events						
# participants affected / at risk	**1/98 (1.02%)**	**0/92 (0.00%)**	**1/101 (0.99%)**	**2/96 (2.08%)**	**1/90 (1.11%)**	**1/91 (1.10%)**
Nervous system disorders						
CEREBROVASCULAR ACCIDENT † 1						
# participants affected / at risk	**0/98 (0.00%)**	**0/92 (0.00%)**	**0/101 (0.00%)**	**1/96 (1.04%)**	**0/90 (0.00%)**	**0/91 (0.00%)**
Psychiatric disorders						
CONFUSIONAL STATE † 1						
# participants affected / at risk	**0/98 (0.00%)**	**0/92 (0.00%)**	**0/101 (0.00%)**	**1/96 (1.04%)**	**0/90 (0.00%)**	**0/91 (0.00%)**
Respiratory, thoracic and mediastinal disorders						
CHRONIC OBSTRUCTIVE PULMONARY DISEASE † 1						
# participants affected / at risk	**1/98 (1.02%)**	**0/92 (0.00%)**	**1/101 (0.99%)**	**1/96 (1.04%)**	**1/90 (1.11%)**	**1/91 (1.10%)**

† 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	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Indacaterol 62.5 µg	Indacaterol 62.5 µg delivered by the TWISTHALER® device once a day and placebo to formoterol (placebo AEROLIZER® device) twice a day for 14 days.
Indacaterol 125 µg	Indacaterol 125 µg delivered by the TWISTHALER® device once a day and placebo to formoterol (placebo AEROLIZER® device) twice a day for 14 days.
Indacaterol 250 µg	Indacaterol 250 µg delivered by the TWISTHALER® device once a day and placebo to formoterol (placebo AEROLIZER® device) twice a day for 14 days.
Indacaterol 500 µg	Indacaterol 500 µg delivered by the TWISTHALER® device once a day and placebo to formoterol (placebo AEROLIZER® device) twice a day for 14 days.
Formoterol	Formoterol 12 µg delivered by the AEROLIZER® device twice a day and placebo to indacaterol (placebo TWISTHALER® device) once a day for 14 days.
Placebo	Placebo to indacaterol (placebo TWISTHALER® placebo) once a day and placebo to formoterol (placebo AEROLIZER® device) twice a day for 14 days.

Other Adverse Events

	Indacaterol 62.5 µg	Indacaterol 125 µg	Indacaterol 250 µg	Indacaterol 500 µg	Formoterol	Placebo
Total, other (not including serious) adverse events						

# participants affected / at risk	**4/98 (4.08%)**	**5/92 (5.43%)**	**3/101 (2.97%)**	**4/96 (4.17%)**	**6/90 (6.67%)**	**8/91 (8.79%)**
Infections and infestations						
NASOPHARYNGITIS † 1						
# participants affected / at risk	**2/98 (2.04%)**	**0/92 (0.00%)**	**1/101 (0.99%)**	**1/96 (1.04%)**	**5/90 (5.56%)**	**2/91 (2.20%)**
Nervous system disorders						
HEADACHE † 1						
# participants affected / at risk	**2/98 (2.04%)**	**5/92 (5.43%)**	**2/101 (1.98%)**	**3/96 (3.13%)**	**1/90 (1.11%)**	**6/91 (6.59%)**

† 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

Responsible Party:	Novartis
ClinicalTrials.gov Identifier:	NCT00557466 History of Changes
Other Study ID Numbers:	**CQMF149B2201**
Study First Received:	November 13, 2007
Results First Received:	November 12, 2012
Last Updated:	December 12, 2012
Health Authority:	Belgium: Federal Agency for Medicinal Products and Health Products France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis) Germany: Federal Institute for Drugs and Medical Devices Hungary: National Institute of Pharmacy Ireland: Irish Medicines Board

Italy: The Italian Medicines Agency
Latvia: State Agency of Medicines
Lithuania: State Medicine Control Agency - Ministry of Health
Norway: Norwegian Medicines Agency
Poland: Office for Registration of Medicinal Products, Medical Devices and Biocidal Products
Romania: National Medicines Agency
South Africa: Medicines Control Council
Sweden: Medical Products Agency
Turkey: Ministry of Health
United Kingdom: Medicines and Healthcare Products Regulatory Agency
Argentina: Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica
Chile: Comisión Nacional de Investigación Científica y Tecnológica
Peru: Ministry of Health