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Trial record **1 of 1** for: CQMF149A2204

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Bronchodilatory Efficacy of a Single Dose QMF149 (Indacaterol Maleate/Mometasone Furoate) Via the Twisthaler® Device in Adult Patients With Asthma

This study has been completed.

Sponsor:
Novartis

Collaborator:
Merck Sharp & Dohme Corp.

Information provided by (Responsible Party):
Novartis

ClinicalTrials.gov Identifier:
NCT00556673

First received: November 9, 2007
Last updated: March 11, 2013
Last verified: March 2013
History of Changes

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Results First Received: March 11, 2013

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Efficacy Study; Intervention Model: Crossover Assignment; Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Asthma

Interventions:	Drug: indacaterol maleate/mometasone furoate Drug: placebo to indacaterol maleate/mometasone furoate Drug: fluticasone proprionate / salmeterol xinafoate

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/Mometasone - Placebo	In Treatment Period 1 (Day 1) participants received 2 inhalations of indacaterol maleate 250 µg/mometasone furoate 200 µg once a day in the morning via the Twisthaler device. In Treatment Period 2 (Day 8) participants received 2 inhalations of placebo via the Twisthaler device once a day in the morning. In Treatment Period 3 (Day 15) participants received fluticasone proprionate 250 µg/salmeterol xinafoate 50 µg twice a day delivered via dry-powder inhaler. Each treatment period was separated by a minimum washout period of 7 days.
Placebo - Indacaterol/Mometasone	In Treatment Period 1 (Day 1) participants received 2 inhalations of placebo in the morning via the Twisthaler device. In Treatment Period 2 (Day 8) participants received 2 inhalations of indacaterol maleate 250 µg/mometasone furoate 200 µg via the Twisthaler device in the morning. In Treatment Period 3 (Day 15) participants received fluticasone proprionate 250 µg/salmeterol xinafoate 50 µg twice a day delivered via dry-powder inhaler. Each treatment period was separated by a minimum washout period of 7 days.

Participant Flow: Overall Study

	Indacaterol/Mometasone - Placebo	Placebo - Indacaterol/Mometasone
STARTED	16	15
Pharmacodynamic (PD) Population	12 [1]	12 [2]
COMPLETED	13	13
NOT COMPLETED	3	2
Protocol deviation	3	2

[1] 4 patients inadvertently unblinded were not included in PD analysis population.
[2] 3 patients inadvertently unblinded were not included in PD analysis population.

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/Mometasone - Placebo	In Treatment Period 1 (Day 1) participants received 2 inhalations of indacaterol maleate 250 µg/mometasone furoate 200 µg once a day in the morning via the Twisthaler device. In Treatment Period 2 (Day 8) participants received 2 inhalations of placebo via the Twisthaler device once a day in the morning. In Treatment Period 3 (Day 15) participants received fluticasone proprionate 250 µg/salmeterol xinafoate 50 µg twice a day delivered via dry-powder inhaler. Each treatment period was separated by a minimum washout period of 7 days.
Placebo - Indacaterol/Mometasone	In Treatment Period 1 (Day 1) participants received 2 inhalations of placebo in the morning via the

	Twisthaler device. In Treatment Period 2 (Day 8) participants received 2 inhalations of indacaterol maleate 250 µg/mometasone furoate 200 µg via the Twisthaler device in the morning. In Treatment Period 3 (Day 15) participants received fluticasone proprionate 250 µg/salmeterol xinafoate 50 µg twice a day delivered via dry-powder inhaler. Each treatment period was separated by a minimum washout period of 7 days.
Total	Total of all reporting groups

Baseline Measures

	Indacaterol/Mometasone - Placebo	Placebo - Indacaterol/Mometasone	Total
Number of Participants [units: participants]	**16**	**15**	**31**
Age [units: years] Mean (Standard Deviation)	**39.1 (11.93)**	**41.5 (7.23)**	**40.3 (9.85)**
Gender [units: participants]			
Female	**9**	**6**	**15**
Male	**7**	**9**	**16**

Outcome Measures

Hide All Outcome Measures

1. Primary: Change From Period Baseline to 24 Hour Post-dose (Trough) Forced Expiratory Volume in 1 Second (FEV1) [Time Frame: Pre-dose for each Treatment Period (Days 1, 8 and 15) and 24-hours post-dose for each Treatment Period (Days 2, 9 and 16).]

Measure Type	Primary
Measure Title	Change From Period 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 the period baseline to 24 hour post dose trough FEV1 after 1 day of treatment was modeled using a linear mixed effect model fitting treatment, sequence and period as fixed factors, patient within sequence as a random factor and pre-dose FEV1 as covariate.
Time Frame	Pre-dose for each Treatment Period (Days 1, 8 and 15) and 24-hours post-dose for each Treatment Period (Days 2, 9 and 16).
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.
Pharmacodynamic population included all patients randomized that received at least one dose of study drug and completed the first two treatment periods with evaluable data for the primary efficacy variable, and with no major protocol deviations. 7 patients who were inadvertently unblinded by the investigator were excluded from the PD analysis.

Reporting Groups

	Description
Indacaterol/Mometasone	Participants received a single dose of indacaterol/mometasone 500/400 µg delivered via the TWISTHALER device (2 inhalations of 250/200 µg) in the morning.
Placebo	Participants received 2 inhalations of placebo to indacaterol/mometasone via the TWISTHALER device in the morning.
Fluticasone/Salmeterol	Participants received fluticasone/salmeterol 250/50 µg via dry powder inhaler (DPI), one inhalation in the morning and one inhalation the following evening.

Measured Values

	Indacaterol/Mometasone	**Placebo**	**Fluticasone/Salmeterol**
Number of Participants Analyzed [units: participants]	**24**	**24**	**24**

Change From Period Baseline to 24 Hour Post-dose (Trough) Forced Expiratory Volume in 1 Second (FEV1) [units: liters] Least Squares Mean (90% Confidence Interval)	**0.27 (0.19 to 0.36)**	**-0.12 (-0.21 to -0.04)**	**0.37 (0.28 to 0.47)**

Statistical Analysis 1 for Change From Period Baseline to 24 Hour Post-dose (Trough) Forced Expiratory Volume in 1 Second (FEV1)

Groups [1]	Indacaterol/Mometasone vs. Placebo
Method [2]	1-sided
P Value [3]	< 0.0001
LS Mean Difference [4]	0.39
90% Confidence Interval	0.28 to 0.51

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The primary hypothesis tested was that the change from period baseline of trough FEV1 for placebo and indacaterol/mometasone was equal. The one-sided alternative was that the increase from period baseline of trough FEV1 for indacaterol/mometasone was higher than for placebo.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Linear mixed effect model fitting treatment, sequence and period as fixed factors, patient within sequence as a random factor and pre-dose FEV1 as covariate. A significance level of 5% was used to determine statistical significance.
[4]	Other relevant estimation information:
	No text entered.

2. Secondary: Change From Baseline in Peak Forced Expiratory Volume in One Second (FEV1) [Time Frame: Days 1, 8 and 15, pre-dose (Baseline) and 5, 15, and 30 minutes, 1, 2, 3, and 4 hours post-dose.]

Measure Type	Secondary
Measure Title	Change From Baseline in Peak Forced Expiratory Volume in One 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. Peak FEV1 is defined as the peak FEV1 between 0 and 4 hours post-dose. The change from baseline in peak FEV1 was modeled using a linear mixed effect model fitting treatment, sequence and period as fixed factors, patient within sequence as a random factor and pre-dose FEV1 as covariate.
Time Frame	Days 1, 8 and 15, pre-dose (Baseline) and 5, 15, and 30 minutes, 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.
Pharmacodynamic population

Reporting Groups

	Description
Indacaterol/Mometasone	Participants received a single dose of indacaterol/mometasone 500/400 µg delivered via the TWISTHALER device (2 inhalations of 250/200 µg) in the morning.
Placebo	Participants received 2 inhalations of placebo to indacaterol/mometasone via the TWISTHALER device in the morning.
Fluticasone/Salmeterol	Participants received fluticasone/salmeterol 250/50 µg via dry powder inhaler (DPI), one inhalation in the morning and one inhalation the following evening.

Measured Values

	Indacaterol/Mometasone	Placebo	Fluticasone/Salmeterol
Number of Participants Analyzed [units: participants]	**24**	**24**	**24**
Change From Baseline in Peak Forced Expiratory Volume in One Second (FEV1) [units: liters] Least Squares Mean (90% Confidence Interval)	**0.64 (0.55 to 0.73)**	**0.26 (0.17 to 0.34)**	**0.62 (0.54 to 0.71)**

No statistical analysis provided for Change From Baseline in Peak Forced Expiratory Volume in One Second (FEV1)

3. Secondary: Change From Period Baseline in Trough Percent Predicted Forced Expiratory Volume in 1 Second (FEV1) [Time Frame: Pre-dose for each Treatment Period (Days 1, 8 and 15) and 24-hours post-dose for each Treatment Period (Days 2, 9 and 16).]

Measure Type	Secondary
Measure Title	Change From Period Baseline in Trough Percent Predicted Forced Expiratory Volume in 1 Second (FEV1)
Measure Description	Trough FEV1 was measured 24 hours post-dose. The FEV1 percent predicted expresses FEV1 as a percentage of the "predicted values" for participants of similar characteristics (height, age, sex, and sometimes race and weight). A positive change from baseline in FEV1 % predicted indicates improvement in lung function. Change from baseline in trough FEV1 % predicted was modeled using a linear mixed effect model fitting treatment, sequence and period as fixed factors, patient within sequence as a random factor and pre-dose value as covariate.
Time Frame	Pre-dose for each Treatment Period (Days 1, 8 and 15) and 24-hours post-dose for each Treatment Period (Days 2, 9 and 16).
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.

Pharmacodynamic population

Reporting Groups

	Description
Indacaterol/Mometasone	Participants received a single dose of indacaterol/mometasone 500/400 µg delivered via the TWISTHALER device (2 inhalations of 250/200 µg) in the morning.
Placebo	Participants received 2 inhalations of placebo to indacaterol/mometasone via the TWISTHALER device in the morning.
Fluticasone/Salmeterol	Participants received fluticasone/salmeterol 250/50 µg via dry powder inhaler (DPI), one inhalation in the morning and one inhalation the following evening.

Measured Values

	Indacaterol/Mometasone	Placebo	Fluticasone/Salmeterol
Number of Participants Analyzed [units: participants]	**24**	**24**	**24**
Change From Period Baseline in Trough Percent Predicted Forced Expiratory Volume in 1 Second (FEV1) [units: Percent of predicted] Least Squares Mean (90% Confidence Interval)	**6.95 (4.68 to 9.22)**	**-2.87 (-5.14 to -0.59)**	**9.85 (7.58 to 12.12)**

No statistical analysis provided for Change From Period Baseline in Trough Percent Predicted Forced Expiratory Volume in 1 Second (FEV1)

4. Secondary: Change From Period Baseline in Peak Percent Predicted Forced Expiratory Volume in 1 Second (FEV1) [Time Frame: Days 1, 8 and 15, pre-dose (Baseline) and 5, 15, and 30 minutes, 1, 2, 3, and 4 hours post-dose.]

Measure Type	Secondary
Measure Title	Change From Period Baseline in Peak Percent Predicted Forced Expiratory Volume in 1 Second (FEV1)

Measure Description	Peak FEV1 was defined as the peak FEV1 up to 4 hours post-dose. The FEV1 percent predicted expresses FEV1 as a percentage of the "predicted values" for participants of similar characteristics (height, age, sex, and sometimes race and weight). A positive change from baseline in FEV1 % predicted indicates improvement in lung function. Change from baseline in peak FEV1 % predicted was modeled using a linear mixed effect model fitting treatment, sequence and period as fixed factors, patient within sequence as a random factor and pre-dose value as covariate.
Time Frame	Days 1, 8 and 15, pre-dose (Baseline) and 5, 15, and 30 minutes, 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.
Pharmacodynamic population

Reporting Groups

	Description
Indacaterol/Mometasone	Participants received a single dose of indacaterol/mometasone 500/400 µg delivered via the TWISTHALER device (2 inhalations of 250/200 µg) in the morning.
Placebo	Participants received 2 inhalations of placebo to indacaterol/mometasone via the TWISTHALER device in the morning.
Fluticasone/Salmeterol	Participants received fluticasone/salmeterol 250/50 µg via dry powder inhaler (DPI), one inhalation in the morning and one inhalation the following evening.

Measured Values

	Indacaterol/Mometasone	**Placebo**	**Fluticasone/Salmeterol**
Number of Participants Analyzed [units: participants]	**24**	**24**	**24**
Change From Period Baseline in Peak Percent Predicted Forced			

Expiratory Volume in 1 Second (FEV1) [units: Percent of predicted] Least Squares Mean (90% Confidence Interval)	**16.27 (14.24 to 18.29)**	**6.85 (4.83 to 8.88)**	**16.49 (14.47 to 18.51)**

No statistical analysis provided for Change From Period Baseline in Peak Percent Predicted Forced Expiratory Volume in 1 Second (FEV1)

5. Secondary: Change From Period Baseline in Trough Forced Vital Capacity (FVC) [Time Frame: Pre-dose for each Treatment Period (Days 1, 8 and 15) and 24-hours post-dose for each Treatment Period (Days 2, 9 and 16).]

Measure Type	Secondary
Measure Title	Change From Period Baseline in Trough Forced Vital Capacity (FVC)
Measure Description	Vital capacity is the amount of air which can be forcibly exhaled from the lungs after taking the deepest breath possible. Trough FVC was measured 24 hours post-dose. Change form baseline in trough FVC was modeled using a linear mixed effect model fitting treatment, sequence and period as fixed factors, patient within sequence as a random factor and pre-dose value as covariate.
Time Frame	Pre-dose for each Treatment Period (Days 1, 8 and 15) and 24-hours post-dose for each Treatment Period (Days 2, 9 and 16).
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.
Pharmacodynamic population

Reporting Groups

	Description
Indacaterol/Mometasone	Participants received a single dose of indacaterol/mometasone 500/400 µg delivered via the TWISTHALER device (2 inhalations of 250/200 µg) in the morning.

Placebo	Participants received 2 inhalations of placebo to indacaterol/mometasone via the TWISTHALER device in the morning.
Fluticasone/Salmeterol	Participants received fluticasone/salmeterol 250/50 µg via dry powder inhaler (DPI), one inhalation in the morning and one inhalation the following evening.

Measured Values

	Indacaterol/Mometasone	**Placebo**	**Fluticasone/Salmeterol**
Number of Participants Analyzed [units: participants]	**24**	**24**	**24**
Change From Period Baseline in Trough Forced Vital Capacity (FVC) [units: liters] Least Squares Mean (90% Confidence Interval)	**0.22 (0.13 to 0.31)**	**-0.14 (-0.23 to -0.05)**	**0.17 (0.08 to 0.27)**

No statistical analysis provided for Change From Period Baseline in Trough Forced Vital Capacity (FVC)

6. Secondary: Change From Period Baseline in Peak Forced Vital Capacity (FVC) [Time Frame: Days 1, 8 and 15, pre-dose (Baseline) and 5, 15, and 30 minutes, 1, 2, 3, and 4 hours post-dose.]

Measure Type	Secondary
Measure Title	Change From Period Baseline in Peak Forced Vital Capacity (FVC)
Measure Description	Vital capacity is the amount of air which can be forcibly exhaled from the lungs after taking the deepest breath possible. Peak FVC was measured up to 4 hours post-dose. Change from baseline in peak FVC was modeled using a linear mixed effect model fitting treatment, sequence and period as fixed factors, patient within sequence as a random factor and pre-dose value as covariate.
Time Frame	Days 1, 8 and 15, pre-dose (Baseline) and 5, 15, and 30 minutes, 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.
Pharmacodynamic population

Reporting Groups

	Description
Indacaterol/Mometasone	Participants received a single dose of indacaterol/mometasone 500/400 µg delivered via the TWISTHALER device (2 inhalations of 250/200 µg) in the morning.
Placebo	Participants received 2 inhalations of placebo to indacaterol/mometasone via the TWISTHALER device in the morning.
Fluticasone/Salmeterol	Participants received fluticasone/salmeterol 250/50 µg via dry powder inhaler (DPI), one inhalation in the morning and one inhalation the following evening.

Measured Values

	Indacaterol/Mometasone	**Placebo**	**Fluticasone/Salmeterol**
Number of Participants Analyzed [units: participants]	**24**	**24**	**24**
Change From Period Baseline in Peak Forced Vital Capacity (FVC) [units: liters] Least Squares Mean (90% Confidence Interval)	**0.47 (0.38 to 0.55)**	**0.20 (0.12 to 0.29)**	**0.35 (0.27 to 0.44)**

No statistical analysis provided for Change From Period Baseline in Peak Forced Vital Capacity (FVC)

7. Secondary: Change From Period Baseline in Trough FEV1/FVC Ratio [Time Frame: Pre-dose for each Treatment Period (Days 1, 8 and 15) and 24-hours post-dose for each Treatment Period (Days 2, 9 and 16).]

Measure Type	Secondary
Measure Title	Change From Period Baseline in Trough FEV1/FVC Ratio
Measure Description	The forced expiratory volume in one second (FEV1)/forced vital capacity (FVC) ratio represents the proportion of a person's vital capacity that they are able to expire in the first second of an expiration. Trough FEV1/FVC was calculated from measurements taken 24 hours post-dose. Change from baseline in trough FEV1/FVC ratio was modeled using a linear mixed effect model fitting treatment, sequence and period as fixed factors, patient within sequence as a random factor and pre-dose value as covariate.
Time Frame	Pre-dose for each Treatment Period (Days 1, 8 and 15) and 24-hours post-dose for each Treatment Period (Days 2, 9 and 16).
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.
Pharmacodynamic population

Reporting Groups

	Description
Indacaterol/Mometasone	Participants received a single dose of indacaterol/mometasone 500/400 µg delivered via the TWISTHALER device (2 inhalations of 250/200 µg) in the morning.
Placebo	Participants received 2 inhalations of placebo to indacaterol/mometasone via the TWISTHALER device in the morning.
Fluticasone/Salmeterol	Participants received fluticasone/salmeterol 250/50 µg via dry powder inhaler (DPI), one inhalation in the morning and one inhalation the following evening.

Measured Values

	Indacaterol/Mometasone	Placebo	Fluticasone/Salmeterol
Number of Participants Analyzed [units: participants]	**24**	**24**	**24**
Change From Period Baseline in Trough FEV1/FVC Ratio [units: ratio] Least Squares Mean (90% Confidence Interval)	**2.50 (2.28 to 2.72)**	**2.15 (1.93 to 2.37)**	**2.65 (2.43 to 2.87)**

No statistical analysis provided for Change From Period Baseline in Trough FEV1/FVC Ratio

8. Secondary: Change From Period Baseline in Peak FEV1/FVC Ratio [Time Frame: Days 1, 8 and 15, pre-dose (Baseline) and 5, 15, and 30 minutes, 1, 2, 3, and 4 hours post-dose.]

Measure Type	Secondary
Measure Title	Change From Period Baseline in Peak FEV1/FVC Ratio
Measure Description	The forced expiratory volume in one second (FEV1)/forced vital capacity (FVC) ratio represents the proportion of a person's vital capacity that they are able to expire in the first second of an expiration. Peak FEV1/FVC was calculated from spirometry measurements taken up to 4 hours post-dose. Change from baseline in peak FEV1/FVC ratio was modeled using a linear mixed effect model fitting treatment, sequence and period as fixed factors, patient within sequence as a random factor and pre-dose value as covariate.
Time Frame	Days 1, 8 and 15, pre-dose (Baseline) and 5, 15, and 30 minutes, 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.
Pharmacodynamic population

Reporting Groups

	Description
Indacaterol/Mometasone	Participants received a single dose of indacaterol/mometasone 500/400 µg delivered via the TWISTHALER device (2 inhalations of 250/200 µg) in the morning.
Placebo	Participants received 2 inhalations of placebo to indacaterol/mometasone via the TWISTHALER device in the morning.
Fluticasone/Salmeterol	Participants received fluticasone/salmeterol 250/50 µg via dry powder inhaler (DPI), one inhalation in the morning and one inhalation the following evening.

Measured Values

	Indacaterol/Mometasone	Placebo	Fluticasone/Salmeterol
Number of Participants Analyzed [units: participants]	**24**	**24**	**24**
Change From Period Baseline in Peak FEV1/FVC Ratio [units: ratio] Least Squares Mean (90% Confidence Interval)	**2.86 (2.63 to 3.10)**	**2.53 (2.30 to 2.76)**	**2.90 (2.67 to 3.14)**

No statistical analysis provided for Change From Period Baseline in Peak FEV1/FVC Ratio

9. Secondary: Area Under the Concentration-time Curve From Time 0 to 12 Hours Post-dose for Mometasone Furoate [Time Frame: Samples were taken pre-dose and at 15 and 30 minutes and 1, 2, 4, and 12 hours post-dose.]

Measure Type	Secondary
Measure Title	Area Under the Concentration-time Curve From Time 0 to 12 Hours Post-dose for Mometasone Furoate
Measure Description	No text entered.
Time Frame	Samples were taken pre-dose and at 15 and 30 minutes and 1, 2, 4, and 12 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.
All participants with evaluable pharmacokinetic (PK) parameter data were included in the PK data analysis.

Reporting Groups

	Description
Indacaterol/Mometasone	Participants received a single dose of indacaterol/mometasone 500/400 µg delivered via the TWISTHALER device (2 inhalations of 250/200 µg) in the morning.

Measured Values

	Indacaterol/Mometasone
Number of Participants Analyzed [units: participants]	**29**
Area Under the Concentration-time Curve From Time 0 to 12 Hours Post-dose for Mometasone Furoate [units: pg*h/mL] Mean (Standard Deviation)	**287 (140)**

No statistical analysis provided for Area Under the Concentration-time Curve From Time 0 to 12 Hours Post-dose for Mometasone Furoate

10. Secondary: Area Under the Concentration-time Curve From Time 0 to 24 Hours Post-dose for Mometasone Furoate [Time Frame: Samples were taken pre-dose and at 15 and 30 minutes and 1, 2, 4, 12 and 24 hours post-dose.]

Measure Type	Secondary
Measure Title	Area Under the Concentration-time Curve From Time 0 to 24 Hours Post-dose for Mometasone Furoate
Measure Description	No text entered.
Time Frame	Samples were taken pre-dose and at 15 and 30 minutes and 1, 2, 4, 12 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.
All participants with evaluable pharmacokinetic (PK) parameter data were included in the PK data analysis.

Reporting Groups

	Description
Indacaterol/Mometasone	Participants received a single dose of indacaterol/mometasone 500/400 µg delivered via the TWISTHALER device (2 inhalations of 250/200 µg) in the morning.

Measured Values

	Indacaterol/Mometasone
Number of Participants Analyzed [units: participants]	**29**
Area Under the Concentration-time Curve From Time 0 to 24 Hours Post-dose for Mometasone Furoate [units: pg*h/mL] Mean (Standard Deviation)	**389 (191)**

No statistical analysis provided for Area Under the Concentration-time Curve From Time 0 to 24 Hours Post-dose for Mometasone Furoate

11. Secondary: Area Under the Concentration-time Curve From Time 0 to 24 Hours Post-dose for Indacaterol [Time Frame: Samples were taken pre-dose and at 15 and 30 minutes and 1, 2, 4, 12 and 24 hours post-dose.]

Measure Type	Secondary
Measure Title	Area Under the Concentration-time Curve From Time 0 to 24 Hours Post-dose for Indacaterol
Measure Description	No text entered.

Time Frame	Samples were taken pre-dose and at 15 and 30 minutes and 1, 2, 4, 12 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.
All participants with evaluable pharmacokinetic (PK) parameter data were included in the PK data analysis.

Reporting Groups

	Description
Indacaterol/Mometasone	Participants received a single dose of indacaterol/mometasone 500/400 µg delivered via the TWISTHALER device (2 inhalations of 250/200 µg) in the morning.

Measured Values

	Indacaterol/Mometasone
Number of Participants Analyzed [units: participants]	**28**
Area Under the Concentration-time Curve From Time 0 to 24 Hours Post-dose for Indacaterol [units: pg*h/mL] Mean (Standard Deviation)	**1331 (712)**

No statistical analysis provided for Area Under the Concentration-time Curve From Time 0 to 24 Hours Post-dose for Indacaterol

12. Secondary: Maximum (Peak) Plasma Concentration (Cmax) of Mometasone Furoate [Time Frame: Samples were taken pre-dose and at 15 and 30 minutes and 1, 2, 4, 12 and 24 hours post-dose.]

Measure Type	Secondary

Measure Title	Maximum (Peak) Plasma Concentration (Cmax) of Mometasone Furoate
Measure Description	No text entered.
Time Frame	Samples were taken pre-dose and at 15 and 30 minutes and 1, 2, 4, 12 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.
All participants with evaluable pharmacokinetic (PK) parameter data were included in the PK data analysis.

Reporting Groups

	Description
Indacaterol/Mometasone	Participants received a single dose of indacaterol/mometasone 500/400 µg delivered via the TWISTHALER device (2 inhalations of 250/200 µg) in the morning.

Measured Values

	Indacaterol/Mometasone
Number of Participants Analyzed [units: participants]	**29**
Maximum (Peak) Plasma Concentration (Cmax) of Mometasone Furoate [units: pg/mL] Mean (Standard Deviation)	**47.3 (20.9)**

No statistical analysis provided for Maximum (Peak) Plasma Concentration (Cmax) of Mometasone Furoate

13. Secondary: Maximum (Peak) Plasma Concentration (Cmax) of Indacaterol [Time Frame: Samples were taken pre-dose and at 15 and 30 minutes and 1, 2, 4, 12 and 24 hours post-dose.]

Measure Type	Secondary
Measure Title	Maximum (Peak) Plasma Concentration (Cmax) of Indacaterol
Measure Description	No text entered.
Time Frame	Samples were taken pre-dose and at 15 and 30 minutes and 1, 2, 4, 12 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.
All participants with evaluable pharmacokinetic (PK) parameter data were included in the PK data analysis.

Reporting Groups

	Description
Indacaterol/Mometasone	Participants received a single dose of indacaterol/mometasone 500/400 µg delivered via the TWISTHALER device (2 inhalations of 250/200 µg) in the morning.

Measured Values

	Indacaterol/Mometasone
Number of Participants Analyzed [units: participants]	**28**
Maximum (Peak) Plasma Concentration (Cmax) of Indacaterol [units: pg/mL] Mean (Standard Deviation)	**289 (133)**

No statistical analysis provided for Maximum (Peak) Plasma Concentration (Cmax) of Indacaterol

14. Secondary: Time to Reach Peak or Maximum Concentration Following Drug Administration for Mometasone Furoate [Time Frame: Samples were taken pre-dose and at 15 and 30 minutes and 1, 2, 4, 12 and 24 hours post-dose.]

Measure Type	Secondary
Measure Title	Time to Reach Peak or Maximum Concentration Following Drug Administration for Mometasone Furoate
Measure Description	No text entered.
Time Frame	Samples were taken pre-dose and at 15 and 30 minutes and 1, 2, 4, 12 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.
All participants with evaluable pharmacokinetic (PK) parameter data were included in the PK data analysis.

Reporting Groups

	Description
Indacaterol/Mometasone	Participants received a single dose of indacaterol/mometasone 500/400 µg delivered via the TWISTHALER device (2 inhalations of 250/200 µg) in the morning.

Measured Values

	Indacaterol/Mometasone
Number of Participants Analyzed [units: participants]	**29**
Time to Reach Peak or Maximum Concentration Following Drug Administration for Mometasone Furoate [units: hours] Median (Full Range)	**1.05 (0.250 to 2.08)**

No statistical analysis provided for Time to Reach Peak or Maximum Concentration Following Drug Administration for Mometasone Furoate

15. Secondary: Time to Reach Peak or Maximum Concentration Following Drug Administration for Indacaterol [Time Frame: Samples were taken pre-dose and at 15 and 30 minutes and 1, 2, 4, 12 and 24 hours post-dose.]

Measure Type	Secondary
Measure Title	Time to Reach Peak or Maximum Concentration Following Drug Administration for Indacaterol
Measure Description	No text entered.
Time Frame	Samples were taken pre-dose and at 15 and 30 minutes and 1, 2, 4, 12 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.
All participants with evaluable pharmacokinetic (PK) parameter data were included in the PK data analysis.

Reporting Groups

	Description
Indacaterol/Mometasone	Participants received a single dose of indacaterol/mometasone 500/400 µg delivered via the TWISTHALER device (2 inhalations of 250/200 µg) in the morning.

Measured Values

	Indacaterol/Mometasone
Number of Participants Analyzed [units: participants]	**28**
Time to Reach Peak or Maximum Concentration Following Drug Administration for Indacaterol [units: hours] Median (Full Range)	**0.325 (0.267 to 0.617)**

No statistical analysis provided for Time to Reach Peak or Maximum Concentration Following Drug Administration for Indacaterol

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Indacaterol/Mometasone	Participants received a single dose of indacaterol/mometasone 500/400 µg delivered via the TWISTHALER device (2 inhalations of 250/200 µg) in the morning.
Placebo	Participants received 2 inhalations of placebo to indacaterol/mometasone via the TWISTHALER device in the morning.
Fluticasone/Salmeterol	Participants received fluticasone/salmeterol 250/50 µg via dry powder inhaler (DPI), one inhalation in the morning and one inhalation the following evening.

Serious Adverse Events

	Indacaterol/Mometasone	Placebo	Fluticasone/Salmeterol
Total, serious adverse events			
# participants affected / at risk	**0/29 (0.00%)**	**0/28 (0.00%)**	**0/26 (0.00%)**

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	0%

Reporting Groups

	Description
Indacaterol/Mometasone	Participants received a single dose of indacaterol/mometasone 500/400 µg delivered via the TWISTHALER device (2 inhalations of 250/200 µg) in the morning.
Placebo	Participants received 2 inhalations of placebo to indacaterol/mometasone via the TWISTHALER device in the morning.
Fluticasone/Salmeterol	Participants received fluticasone/salmeterol 250/50 µg via dry powder inhaler (DPI), one inhalation in the morning and one inhalation the following evening.

Other Adverse Events

	Indacaterol/Mometasone	Placebo	Fluticasone/Salmeterol
Total, other (not including serious) adverse events			
# participants affected / at risk	**10/29 (34.48%)**	**6/28 (21.43%)**	**2/26 (7.69%)**
Gastrointestinal disorders			
Dyspepsia †			
# participants affected / at risk	**0/29 (0.00%)**	**1/28 (3.57%)**	**0/26 (0.00%)**
Nausea †			
# participants affected / at risk	**1/29 (3.45%)**	**0/28 (0.00%)**	**0/26 (0.00%)**
Tongue coated †			

# participants affected / at risk	1/29 (3.45%)	1/28 (3.57%)	0/26 (0.00%)
General disorders			
Catheter site haematoma †			
# participants affected / at risk	1/29 (3.45%)	0/28 (0.00%)	0/26 (0.00%)
Infections and infestations			
Nasopharyngitis †			
# participants affected / at risk	0/29 (0.00%)	0/28 (0.00%)	1/26 (3.85%)
Oral candidiasis †			
# participants affected / at risk	1/29 (3.45%)	0/28 (0.00%)	0/26 (0.00%)
Rhinitis †			
# participants affected / at risk	0/29 (0.00%)	1/28 (3.57%)	0/26 (0.00%)
Vulvovaginal mycotic infection †			
# participants affected / at risk	1/29 (3.45%)	0/28 (0.00%)	0/26 (0.00%)
Musculoskeletal and connective tissue disorders			
Neck pain †			
# participants affected / at risk	1/29 (3.45%)	0/28 (0.00%)	0/26 (0.00%)
Torticollis †			
# participants affected / at risk	0/29 (0.00%)	1/28 (3.57%)	0/26 (0.00%)
Nervous system disorders			
Headache †			
# participants affected / at risk	4/29 (13.79%)	3/28 (10.71%)	1/26 (3.85%)
Psychiatric disorders			
Restlessness †			
# participants affected / at risk	1/29 (3.45%)	0/28 (0.00%)	0/26 (0.00%)
Reproductive system and breast disorders			

Premenstrual syndrome †			
# participants affected / at risk	**1/29 (3.45%)**	**0/28 (0.00%)**	**0/26 (0.00%)**
Respiratory, thoracic and mediastinal disorders			
Cough †			
# participants affected / at risk	**5/29 (17.24%)**	**1/28 (3.57%)**	**0/26 (0.00%)**

† Events were collected by systematic assessment

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:	NCT00556673 History of Changes
Other Study ID Numbers:	**CQMF149A2204** 2007-002360-10 (EudraCT Number)
Study First Received:	November 9, 2007
Results First Received:	March 11, 2013
Last Updated:	March 11, 2013
Health Authority:	France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis) Germany: Federal Institute for Drugs and Medical Devices