Trial record **1 of 1** for: CQMF149A2202

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Investigation of the 24 Hour Forced Expiratory Flow in 1 Second (FEV1) Profile of a Single Dose of Indacaterol/Mometasone Delivered Via the TWISTHALER® Device in Adult Patients With Persistent Asthma

This study has been completed.

Sponsor:
Novartis

Information provided by (Responsible Party):
Novartis

ClinicalTrials.gov Identifier:
NCT00557440

First received: November 12, 2007
Last updated: February 15, 2013
Last verified: April 2009
History of Changes

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Results First Received: February 15, 2013

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Crossover Assignment; Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Asthma
	Drug: fluticasone propionate/salmeterol Drug: indacaterol maleate / mometasone furoate

Interventions:	Drug: placebo to indacaterol/mometasone Drug: placebo to fluticasone propionate/salmeterol

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
Ind/M - FP/Salm - Pbo	In Treatment Period 1 (Days 1 & 2) participants received indacaterol/mometasone (Ind/M) 500/400 µg via the TWISTHALER device (2 inhalations of 250/200 µg) in the evening and placebo to fluticasone/salmeterol via multi-dose dry powder inhaler (MDDPI), one inhalation in the evening and one inhalation the following morning. In Treatment Period 2 (Days 8 & 9) participants received 2 inhalations of placebo to indacaterol/mometasone via the TWISTHALER device in the evening and fluticasone /salmeterol (FP/Salm) 250/50 µg via MDDPI, one inhalation in the evening and one inhalation the following morning. In Treatment Period 3 (Days 15 & 16) participants received 2 inhalations of placebo (Pbo) to indacaterol/mometasone via the TWISTHALER device in the evening and placebo to fluticasone/salmeterol via MDDPI, one inhalation in the evening and one inhalation the following morning. Each treatment period was separated by a 6-day washout period.
FP/Salm - Pbo - Ind/M	In Treatment Period 1 (Days 1 & 2) participants received 2 inhalations of placebo to indacaterol/mometasone via the TWISTHALER device in the evening and fluticasone/salmeterol (FP/Salm) 250/50 µg via MDDPI, one inhalation in

	the evening and one inhalation the following morning. In Treatment Period 2 (Days 8 & 9) participants received 2 inhalations of placebo to indacaterol/mometasone via the TWISTHALER device in the evening and placebo to fluticasone/salmeterol via MDDPI, one inhalation in the evening and one inhalation the following morning. In Treatment Period 3 (Days 15 & 16) participants received indacaterol/mometasone (Ind/M) 500/400 µg via the TWISTHALER device (2 inhalations of 250/200 µg) in the evening and placebo to fluticasone/salmeterol via MDDPI, one inhalation in the evening and one inhalation the following morning. Each treatment period was separated by a 6-day washout period.
Pbo - Ind/M - FP/Salm	In Treatment Period 1 (Days 1 & 2) participants received 2 inhalations of placebo (Pbo) to indacaterol/mometasone via the TWISTHALER device in the evening and placebo to fluticasone/salmeterol via MDDPI, one inhalation in the evening and one inhalation the following morning. In Treatment Period 2 (Days 8 & 9) participants received indacaterol/mometasone (Ind/M) 500/400 µg via the TWISTHALER device (2 inhalations of 250/200 µg) in the evening and placebo to fluticasone/salmeterol via MDDPI, one inhalation in the evening and one inhalation the following morning. In Treatment Period 3 (Days 15 & 16) participants received 2 inhalations of placebo to indacaterol/mometasone via the TWISTHALER device in the evening and fluticasone/salmeterol (FP/Salm) 250/50 µg via MDDPI, one inhalation in the evening and one inhalation the following morning. Each treatment period was separated by a 6-day washout period.

Participant Flow for 3 periods

Period 1: Treatment Period 1

	Ind/M - FP/Salm - Pbo	FP/Salm - Pbo - Ind/M	Pbo - Ind/M - FP/Salm
STARTED	**12**	**12**	**13**
COMPLETED	**12**	**12**	**12**
NOT COMPLETED	**0**	**0**	**1**
Adverse Event	**0**	**0**	**1**

Period 2: Treatment Period 2

	Ind/M - FP/Salm - Pbo	FP/Salm - Pbo - Ind/M	Pbo - Ind/M - FP/Salm
STARTED	12	12	12
COMPLETED	12	12	12
NOT COMPLETED	0	0	0

Period 3: Treatment Period 3

	Ind/M - FP/Salm - Pbo	FP/Salm - Pbo - Ind/M	Pbo - Ind/M - FP/Salm
STARTED	12	12	12
COMPLETED	12	12	12
NOT COMPLETED	0	0	0

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
Ind/M - FP/Salm - Pbo	In Treatment Period 1 (Days 1 & 2) participants received indacaterol/mometasone (Ind/M) 500/400 µg via the TWISTHALER device (2 inhalations of 250/200 µg) in the evening and placebo to fluticasone/salmeterol via multi-dose dry powder inhaler (MDDPI), one inhalation in the evening and one inhalation the following morning. In Treatment Period 2 (Days 8 & 9) participants received 2 inhalations of placebo to indacaterol/mometasone via the TWISTHALER device in the evening and fluticasone /salmeterol (FP/Salm) 250/50 µg via MDDPI, one inhalation in the evening and one inhalation the following morning.

	In Treatment Period 3 (Days 15 & 16) participants received 2 inhalations of placebo (Pbo) to indacaterol/mometasone via the TWISTHALER device in the evening and placebo to fluticasone/salmeterol via MDDPI, one inhalation in the evening and one inhalation the following morning. Each treatment period was separated by a 6-day washout period.
FP/Salm - Pbo - Ind/M	In Treatment Period 1 (Days 1 & 2) participants received 2 inhalations of placebo to indacaterol/mometasone via the TWISTHALER device in the evening and fluticasone/salmeterol (FP/Salm) 250/50 µg via MDDPI, one inhalation in the evening and one inhalation the following morning. In Treatment Period 2 (Days 8 & 9) participants received 2 inhalations of placebo to indacaterol/mometasone via the TWISTHALER device in the evening and placebo to fluticasone/salmeterol via MDDPI, one inhalation in the evening and one inhalation the following morning. In Treatment Period 3 (Days 15 & 16) participants received indacaterol/mometasone (Ind/M) 500/400 µg via the TWISTHALER device (2 inhalations of 250/200 µg) in the evening and placebo to fluticasone/salmeterol via MDDPI, one inhalation in the evening and one inhalation the following morning. Each treatment period was separated by a 6-day washout period.
Pbo - Ind/M - FP/Salm	In Treatment Period 1 (Days 1 & 2) participants received 2 inhalations of placebo (Pbo) to indacaterol/mometasone via the TWISTHALER device in the evening and placebo to fluticasone/salmeterol via MDDPI, one inhalation in the evening and one inhalation the following morning. In Treatment Period 2 (Days 8 & 9) participants received indacaterol/mometasone (Ind/M) 500/400 µg via the TWISTHALER device (2 inhalations of 250/200 µg) in the evening and placebo to fluticasone/salmeterol via MDDPI, one inhalation in the evening and one inhalation the following morning. In Treatment Period 3 (Days 15 & 16) participants received 2 inhalations of placebo to indacaterol/mometasone via the TWISTHALER device in the evening and fluticasone/salmeterol (FP/Salm) 250/50 µg via MDDPI, one inhalation in the evening and one inhalation the following morning. Each treatment period was separated by a 6-day washout period.
Total	Total of all reporting groups

Baseline Measures

	Ind/M - FP/Salm - Pbo	FP/Salm - Pbo - Ind/M	Pbo - Ind/M - FP/Salm	Total
Number of Participants [units: participants]	**12**	**12**	**13**	**37**

Age [units: years] Mean (Standard Deviation)	**40.2 (15.37)**	**50.5 (12.00)**	**52.5 (10.46)**	**47.9 (13.51)**
Gender [units: participants]				
Female	**5**	**3**	**7**	**15**
Male	**7**	**9**	**6**	**22**

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 analyzed using Analysis of Covariance (ANCOVA) adjusting for treatment, period, sequence and center with period baseline as a covariate and patient nested within sequence as a random effect.
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.
The Intent-To-Treat (ITT) population included all randomized patients who had at least one period containing a Baseline FEV1 measurement

and at least one post-baseline measurement of FEV1 for the same treatment period. Patients who took rescue medication within 6 hours prior to the trough measurements were excluded from the 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 evening.
Fluticasone/Salmeterol	Participants received fluticasone/salmeterol 250/50 µg via multi-dose dry powder inhaler (MDDPI), one inhalation in the evening and one inhalation the following morning.
Placebo	Participants received placebo to indacaterol/mometasone via the TWISTHALER device and placebo to fluticasone/salmeterol via MDDPI.

Measured Values

	Indacaterol/Mometasone	Fluticasone/Salmeterol	Placebo
Number of Participants Analyzed [units: participants]	**36**	**36**	**35**
Change From Period Baseline to 24 Hour Post-dose (Trough) Forced Expiratory Volume in 1 Second (FEV1) [units: liters] Least Squares Mean (Standard Error)	**0.081 (0.0473)**	**0.049 (0.0472)**	**-0.083 (0.0475)**

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]	ANCOVA
P Value [3]	0.001

LS Mean Difference [4]	0.165
Standard Error of the mean	(0.0492)
95% Confidence Interval	0.066 to 0.263

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Treatment, period, sequence and center as fixed effects, period baseline FEV1 as a covariate, and patient nested within sequence as a random effect.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Statistical significance (two-sided) at 5% level. p-values were not corrected for multiplicity.
[4]	Other relevant estimation information:
	No text entered.

2. Secondary: Forced Expiratory Volume in 1 Second (FEV1) at Single Time Points [Time Frame: 5, 30 minutes, 1, 2, 3, 4 hours, 11 hours 10 minutes, 11 hours 45 minutes, 12 hours 30 minutes, 14, 16, 18, 20, 22 hours, 23 hours 10 minutes, and 23 hours 45 minutes post-dosing.]

Measure Type	Secondary
Measure Title	Forced Expiratory Volume in 1 Second (FEV1) at Single Time Points
Measure Description	FEV1 is the amount of air which can be forcibly exhaled from the lungs in the first second of a forced exhalation. FEV1 was analyzed using Analysis of Covariance (ANCOVA) adjusting for treatment, period, sequence and center with period baseline as a covariate and patient nested within sequence as a random effect.
Time Frame	5, 30 minutes, 1, 2, 3, 4 hours, 11 hours 10 minutes, 11 hours 45 minutes, 12 hours 30 minutes, 14, 16, 18, 20, 22 hours, 23 hours 10 minutes, and 23 hours 45 minutes post-dosing.

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, where data were available. Patients who took rescue medication within 6 hours prior to spirometry measurements were excluded from the analysis. N indicates the number of participants with available data at each time point.

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

Measured Values

	Indacaterol/Mometasone	**Fluticasone/Salmeterol**	**Placebo**
Number of Participants Analyzed [units: participants]	**36**	**36**	**37**
Forced Expiratory Volume in 1 Second (FEV1) at Single Time Points [units: liters] Least Squares Mean (Standard Error)			
5 minutes [N=36, 36, 37]	**2.713 (0.0302)**	**2.632 (0.0302)**	**2.554 (0.0300)**
30 minutes [N=36, 36, 36]	**2.754 (0.0316)**	**2.719 (0.0316)**	**2.527 (0.0316)**

1 hour [N=36, 36, 36]	**2.760 (0.0350)**	**2.771 (0.0350)**	**2.525 (0.0350)**
2 hours [N=36, 36, 36]	**2.754 (0.0400)**	**2.734 (0.0399)**	**2.483 (0.0400)**
3 hours [N=36, 36, 36]	**2.728 (0.0411)**	**2.724 (0.0410)**	**2.425 (0.0411)**
4 hours [N=36, 36, 35]	**2.705 (0.0434)**	**2.669 (0.0434)**	**2.376 (0.0437)**
11 hours 10 minutes [N=36, 35, 34]	**2.685 (0.0496)**	**2.570 (0.0499)**	**2.295 (0.0505)**
11 hours 45 minutes [N=36, 35, 32]	**2.628 (0.0492)**	**2.518 (0.0495)**	**2.276 (0.0509)**
12 hours 30 minutes [N=36, 35, 32]	**2.667 (0.0437)**	**2.659 (0.0440)**	**2.359 (0.0453)**
14 hours [N=36, 35, 32]	**2.766 (0.0433)**	**2.779 (0.0436)**	**2.485 (0.0448)**
16 hours [N=36, 35, 31]	**2.720 (0.0493)**	**2.681 (0.0497)**	**2.454 (0.0515)**
18 hours [N=35, 36, 33]	**2.729 (0.0395)**	**2.717 (0.0389)**	**2.513 (0.0398)**
20 hours [N=35, 36, 34]	**2.725 (0.0475)**	**2.707 (0.0467)**	**2.479 (0.0475)**
22 hours [N=35, 36, 34]	**2.674 (0.0493)**	**2.695 (0.0485)**	**2.487 (0.0493)**
23 hours 10 minutes [N=35, 36, 35]	**2.696 (0.0517)**	**2.676 (0.0510)**	**2.530 (0.0513)**
23 hours 45 minutes [N=36, 36, 34]	**2.686 (0.0459)**	**2.640 (0.0458)**	**2.523 (0.0464)**

24 hours post-dose trough [N=36, 36, 35]	**2.689 (0.0473)**	**2.656 (0.0472)**	**2.524 (0.0475)**

No statistical analysis provided for Forced Expiratory Volume in 1 Second (FEV1) at Single Time Points

3. Secondary: Forced Expiratory Volume in 1 Second (FEV1) Standardized Area Under the Curve (AUC) Between Baseline (Pre-dose) and 24 Hours Post-dose [Time Frame: Pre-dose, 5, 30 minutes, 1, 2, 3, 4 hours, 11 hours 10 minutes, 11 hours 45 minutes, 12 hours 30 minutes, 14, 16, 18, 20, 22 hours, 23 hours 10 minutes, and 23 hours 45 minutes post-dosing.]

Measure Type	Secondary
Measure Title	Forced Expiratory Volume in 1 Second (FEV1) Standardized Area Under the Curve (AUC) Between Baseline (Pre-dose) and 24 Hours Post-dose
Measure Description	FEV1 is the amount of air which can be forcibly exhaled from the lungs in the first second of a forced exhalation. FEV1 was measured pre-dose and up to 24 hours post-dose. The FEV1 standardized area under the curve (AUC) was analyzed for four time intervals: • Baseline (pre-dose) to 4 hours (hr) post-dosing; • Baseline (pre-dose) to 23 hours, 45 minutes (min) post-dosing; • 11 hours, 10 minutes to 12 hours, 30 minutes post-dosing; • 11 hours, 10 minutes to 23 hours, 45 minutes post-dosing. AUC for FEV1 was analyzed using Analysis of Covariance adjusting for treatment, period, sequence and center with period baseline as a covariate and patient nested within sequence as a random effect.
Time Frame	Pre-dose, 5, 30 minutes, 1, 2, 3, 4 hours, 11 hours 10 minutes, 11 hours 45 minutes, 12 hours 30 minutes, 14, 16, 18, 20, 22 hours, 23 hours 10 minutes, and 23 hours 45 minutes post-dosing.
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, where data were available. Patients who took rescue medication within 6 hours prior to spirometry measurements were excluded from the analysis. N indicates the number of participants with available data at each time point.

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

Measured Values

	Indacaterol/Mometasone	Fluticasone/Salmeterol	Placebo
Number of Participants Analyzed [units: participants]	**36**	**36**	**37**
Forced Expiratory Volume in 1 Second (FEV1) Standardized Area Under the Curve (AUC) Between Baseline (Pre-dose) and 24 Hours Post-dose [units: liters] Least Squares Mean (Standard Error)			
Baseline to 4 hours [N=36, 36, 37]	**2.730 (0.0327)**	**2.713 (0.0327)**	**2.469 (0.0326)**
Baseline to 23 hours, 45 minutes [N=36, 36, 37]	**2.718 (0.0376)**	**2.679 (0.0376)**	**2.430 (0.0374)**
11 hr, 10 min to 12 hr, 30 min [N=36, 35, 34]	**2.667 (0.0443)**	**2.585 (0.0445)**	**2.314 (0.0451)**

11 hr, 10 min to 23 hr, 45min [N=36, 36, 36]	**2.726 (0.0435)**	**2.696 (0.0435)**	**2.470 (0.0436)**

No statistical analysis provided for Forced Expiratory Volume in 1 Second (FEV1) Standardized Area Under the Curve (AUC) Between Baseline (Pre-dose) and 24 Hours Post-dose

4. Secondary: Time to Peak Forced Expiratory Volume in 1 Second (FEV1) [Time Frame: Up to 4 hours post-dose]

Measure Type	Secondary
Measure Title	Time to Peak 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. Time to peak FEV1 is calculated in minutes from the time of inhalation of study drug to the time of the peak FEV1 during the first 4 hours post-dose. Time to peak FEV1 is based on log-transformed analysis of variance adjusted for treatment, period, sequence and center, with patient nested within sequence as a random effect. Geometric Mean was obtained by taking anti-logs of the adjusted means from the model and standard error was calculated using the delta method.
Time Frame	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.
Intent-to-treat population, where data were available. Patients who took rescue medication within 6 hours prior to spirometry measurements were excluded from the 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 evening.
Fluticasone/Salmeterol	Participants received fluticasone/salmeterol 250/50 µg via multi-dose dry powder inhaler (MDDPI), one inhalation in the evening and one inhalation the following morning.
Placebo	Participants received placebo to indacaterol/mometasone via the TWISTHALER device and placebo to fluticasone/salmeterol via MDDPI.

Measured Values

	Indacaterol/Mometasone	**Fluticasone/Salmeterol**	**Placebo**
Number of Participants Analyzed [units: participants]	**36**	**36**	**37**
Time to Peak Forced Expiratory Volume in 1 Second (FEV1) [units: minutes] Geometric Mean (Standard Error)	**87.4 (16.98)**	**67.7 (13.16)**	**22.3 (4.30)**

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

5. Secondary: Forced Vital Capacity (FVC) at Single Time Points [Time Frame: 5, 30 minutes, 1, 2, 3, 4 hours, 11 hours 10 minutes, 11 hours 45 minutes, 12 hours 30 minutes, 14, 16, 18, 20, 22 hours, 23 hours 10 minutes, and 23 hours 45 minutes post-dosing.]

Measure Type	Secondary
Measure Title	Forced Vital Capacity (FVC) at Single Time Points
Measure Description	Vital capacity is the amount of air which can be forcibly exhaled from the lungs after taking the deepest breath possible. FVC was analyzed using ANCOVA adjusting for treatment, period, sequence and center with period baseline as a covariate and patient nested within sequence as a random effect.
Time Frame	5, 30 minutes, 1, 2, 3, 4 hours, 11 hours 10 minutes, 11 hours 45 minutes, 12 hours 30 minutes, 14, 16, 18, 20, 22 hours, 23 hours 10 minutes, and 23 hours 45 minutes post-dosing.

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, where data were available. Patients who took rescue medication within 6 hours prior to spirometry measurements were excluded from the analysis. N indicates the number of participants with available data at each time point.

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

Measured Values

	Indacaterol/Mometasone	**Fluticasone/Salmeterol**	**Placebo**
Number of Participants Analyzed [units: participants]	**36**	**36**	**37**
Forced Vital Capacity (FVC) at Single Time Points [units: liters] Least Squares Mean (Standard Error)			
5 minutes [N= 36, 36, 37]	**3.917 (0.0333)**	**3.880 (0.0333)**	**3.830 (0.0331)**
30 minutes [N= 36, 36, 36]	**3.946 (0.0338)**	**3.933 (0.0338)**	**3.839 (0.0338)**
1 hour [N= 36, 36, 36]	**3.945 (0.0337)**	**3.955 (0.0337)**	**3.808 (0.0337)**
2 hours [N= 36, 36, 36]	**4.080 (0.1074)**	**3.899 (0.1073)**	**3.742 (0.1073)**

3 hours [N= 36, 36, 36]	**3.925 (0.0390)**	**3.923 (0.0390)**	**3.708 (0.0391)**
4 hours [N= 36, 36, 35]	**3.857 (0.0438)**	**3.861 (0.0438)**	**3.665 (0.0442)**
11 hours 10 minutes [N= 36, 35, 34]	**3.896 (0.0569)**	**3.828 (0.0573)**	**3.632 (0.0581)**
11 hours 45 minutes [N= 36, 35, 32]	**3.837 (0.0549)**	**3.736 (0.0553)**	**3.607 (0.0570)**
12 hours 30 minutes [N= 36, 35, 32]	**3.833 (0.0496)**	**3.841 (0.0500)**	**3.680 (0.0518)**
14 hours [N= 36, 35, 32]	**3.918 (0.0506)**	**3.894 (0.0510)**	**3.759 (0.0528)**
16 hours [N= 36, 35, 31]	**3.896 (0.0524)**	**3.787 (0.0528)**	**3.737 (0.0551)**
18 hours [N= 35, 36, 33]	**3.893 (0.0462)**	**3.866 (0.0455)**	**3.784 (0.0466)**
20 hours [N= 35, 36, 34]	**3.903 (0.0499)**	**3.848 (0.0492)**	**3.764 (0.0499)**
22 hours [N= 35, 36, 34]	**3.865 (0.0453)**	**3.906 (0.0446)**	**3.764 (0.0453)**
23 hours 10 minutes [N= 35, 36, 35]	**3.870 (0.0519)**	**3.866 (0.0512)**	**3.808 (0.0516)**
23 hours 45 minutes [N=36, 36, 34]	**3.866 (0.0509)**	**3.825 (0.0509)**	**3.817 (0.0516)**

No statistical analysis provided for Forced Vital Capacity (FVC) at Single Time Points

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

Serious Adverse Events

	Indacaterol/Mometasone	Fluticasone/Salmeterol	Placebo
Total, serious adverse events			
# participants affected / at risk	**0/36 (0.00%)**	**0/36 (0.00%)**	**0/37 (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	5%

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 evening.
Fluticasone/Salmeterol	Participants received fluticasone/salmeterol 250/50 µg via multi-dose dry powder inhaler (MDDPI), one inhalation in the evening and one inhalation the following morning.

Placebo	Participants received placebo to indacaterol/mometasone via the TWISTHALER device and placebo to fluticasone/salmeterol via MDDPI.

Other Adverse Events

	Indacaterol/Mometasone	Fluticasone/Salmeterol	Placebo
Total, other (not including serious) adverse events			
# participants affected / at risk	**2/36 (5.56%)**	**1/36 (2.78%)**	**2/37 (5.41%)**
Nervous system disorders			
Headache † 1			
# participants affected / at risk	**2/36 (5.56%)**	**1/36 (2.78%)**	**2/37 (5.41%)**

† 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:	NCT00557440 History of Changes
Other Study ID Numbers:	**CQMF149A2202**
Study First Received:	November 12, 2007
Results First Received:	February 15, 2013
Last Updated:	February 15, 2013
Health Authority:	Belgium: Federal Agency for Medicinal Products and Health Products Germany: Federal Institute for Drugs and Medical Devices