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Trial record **1 of 1** for: CQMF149A2203

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Safety and Tolerability of Indacaterol Maleate/Mometasone Furoate Delivered Via the Twisthaler® Device After 14 Days Treatment in Patients With Mild to Moderate Asthma

This study has been completed.

Sponsor:
Novartis

Collaborator:
Merck Sharp & Dohme Corp.

Information provided by (Responsible Party):
Novartis

ClinicalTrials.gov Identifier:
NCT00605306

First received: January 18, 2008
Last updated: March 11, 2013
Last verified: March 2013
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Results First Received: March 11, 2013

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Condition:	Asthma
Interventions:	Drug: indacaterol maleate / mometasone furoate

	Drug: placebo to indacaterol maleate/mometasone furoate

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 Maleate/Mometasone Furoate	Participants received 2 inhalations of indacaterol maleate / mometasone furoate 250/400 µg once daily in the evening (full dose 500/800 µg) delivered via the Twisthaler device for 14 days.
Placebo	Participants received 2 inhalations of placebo to indacaterol maleate / mometasone furoate once daily in the evening delivered via the Twisthaler device for 14 days.

Participant Flow: Overall Study

	Indacaterol Maleate/Mometasone Furoate	Placebo
STARTED	**14**	**14**
COMPLETED	**14**	**13**
NOT COMPLETED	**0**	**1**
Adverse Event	**0**	**1**

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 Maleate/Mometasone Furoate	Participants received 2 inhalations of indacaterol maleate / mometasone furoate 250/400 µg once daily in the evening (full dose 500/800 µg) delivered via the Twisthaler device for 14 days.
Placebo	Participants received 2 inhalations of placebo to indacaterol maleate / mometasone furoate once daily in the evening delivered via the Twisthaler device for 14 days.
Total	Total of all reporting groups

Baseline Measures

	Indacaterol Maleate/Mometasone Furoate	**Placebo**	**Total**
Number of Participants [units: participants]	**14**	**14**	**28**
Age [units: years] Mean (Standard Deviation)	**31.0 (7.18)**	**33.9 (13.35)**	**32.4 (10.62)**
Gender [units: participants]			
Female	**7**	**6**	**13**
Male	**7**	**8**	**15**

Outcome Measures

Hide All Outcome Measures

1. Primary: Participants With Adverse Events [Time Frame: 15 days]

Measure Type	Primary
Measure Title	Participants With Adverse Events
Measure Description	An adverse event (AE) is the appearance or worsening of any undesirable sign, symptom, or medical condition occurring after starting the study drug even if the event is not considered to be related to study drug. Abnormal laboratory values or test results constitute adverse events only if they induce clinical signs or symptoms, are considered clinically significant, or require intervention. A serious adverse event (SAE) is defined as an event which is fatal or life-threatening, results in persistent or significant disability/incapacity, constitutes a congenital anomaly/birth defect, requires inpatient hospitalization or prolongation of existing hospitalization, or is medically significant, i.e., defined as an event that jeopardizes the participant or may require medical or surgical intervention to prevent one of the outcomes listed above.
Time Frame	15 days
Safety Issue	Yes

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

Reporting Groups

	Description
Indacaterol Maleate/Mometasone Furoate	Participants received 2 inhalations of indacaterol maleate / mometasone furoate 250/400 µg once daily in the evening (full dose 500/800 µg) delivered via the Twisthaler device for 14 days.

Placebo	Participants received 2 inhalations of placebo to indacaterol maleate / mometasone furoate once daily in the evening delivered via the Twisthaler device for 14 days.

Measured Values

	Indacaterol Maleate/Mometasone Furoate	Placebo
Number of Participants Analyzed [units: participants]	**14**	**14**
Participants With Adverse Events [units: participants]		
Any adverse event	**9**	**12**
Serious adverse event	**0**	**0**
AE resulting in discontinuation	**0**	**1**

No statistical analysis provided for Participants With Adverse Events

2. Secondary: Levels of Serum Potassium Over Time [Time Frame: Baseline; Days 1 and 14 at pre-dose, 0.25, 0.5, 1, 2, 4 hours post-dose; 12 and 24 hours post-dose (Day 2); study completion (5-9 days after last dose, Day 19-23).]

Measure Type	Secondary
Measure Title	Levels of Serum Potassium Over Time
Measure Description	At the specified time-points, blood samples were collected for measurement of serum potassium and the samples analyzed by a central laboratory. The end of study visit was conducted approximately 5-9 days after the last dose.
Time Frame	Baseline; Days 1 and 14 at pre-dose, 0.25, 0.5, 1, 2, 4 hours post-dose; 12 and 24 hours post-dose (Day 2); study completion (5-9 days after last dose, Day 19-23).
Safety Issue	Yes

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

Reporting Groups

	Description
Indacaterol Maleate/Mometasone Furoate	Participants received 2 inhalations of indacaterol maleate / mometasone furoate 250/400 µg once daily in the evening (full dose 500/800 µg) delivered via the Twisthaler device for 14 days.
Placebo	Participants received 2 inhalations of placebo to indacaterol maleate / mometasone furoate once daily in the evening delivered via the Twisthaler device for 14 days.

Measured Values

	Indacaterol Maleate/Mometasone Furoate	**Placebo**
Number of Participants Analyzed [units: participants]	**14**	**14**
Levels of Serum Potassium Over Time [units: mmol/L] Mean (Standard Deviation)		
Baseline (N=14, 14)	**4.271 (0.2867)**	**4.336 (0.3388)**
Day 1, pre-dose (N=14, 14)	**4.264 (0.2240)**	**4.279 (0.3446)**
Day 1, 0.25 hours post-dose (N=14, 14)	**4.293 (0.3583)**	**4.314 (0.5803)**
Day 1, 0.5 hours post-dose (N=14, 14)	**4.150 (0.2442)**	**4.179 (0.3093)**
Day 1, 1 hour post-dose (N=14, 14)	**4.143 (0.2174)**	**4.171 (0.2614)**
Day 1, 2 hours post-dose (N=14, 14)	**4.157 (0.2709)**	**4.093 (0.2200)**
Day 1, 4 hours post-dose (N=14, 14)	**3.979 (0.2486)**	**3.929 (0.2494)**
Day 2, 12 hours post-dose (N=14, 14)	**4.436 (0.2530)**	**4.500 (0.2961)**

Day 2, 24 hours post-dose (N=14, 14)	**4.293 (0.2786)**	**4.386 (0.4753)**
Day 14, pre-dose (N=14, 14)	**4.150 (0.3205)**	**4.136 (0.3079)**
Day 14, 0.25 hours post-dose (N=14, 13)	**4.064 (0.3522)**	**4.092 (0.3353)**
Day 14, 0.5 hours post-dose (N=14, 13)	**3.986 (0.3325)**	**4.092 (0.3378)**
Day 14, 1 hour post-dose (N=14, 13)	**3.986 (0.3880)**	**4.038 (0.4426)**
Day 14, 2 hours post-dose (N=14, 13)	**3.986 (0.2627)**	**4.038 (0.3927)**
Day 14, 4 hours post-dose (N=14, 13)	**3.800 (0.3397)**	**3.792 (0.2397)**
End of study (N=14, 14)	**4.364 (0.2373)**	**4.429 (0.4103)**

No statistical analysis provided for Levels of Serum Potassium Over Time

3. Secondary: Levels of Plasma Glucose Over Time [Time Frame: Baseline; Days 1 and 14 at pre-dose, 0.25, 0.5, 1, 2, 4 hours post-dose; 12 and 24 hours post dose (Day 2); study completion (5-9 days after last dose, Day 19-23).]

Measure Type	Secondary
Measure Title	Levels of Plasma Glucose Over Time
Measure Description	At the specified time-points, blood samples were collected for measurement of plasma glucose and the samples analyzed by a central laboratory. The end of study visit was conducted approximately 5-9 days after the last dose.
Time Frame	Baseline; Days 1 and 14 at pre-dose, 0.25, 0.5, 1, 2, 4 hours post-dose; 12 and 24 hours post dose (Day 2); study completion (5-9 days after last dose, Day 19-23).
Safety Issue	Yes

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

Reporting Groups

	Description
Indacaterol Maleate/Mometasone Furoate	Participants received 2 inhalations of indacaterol maleate / mometasone furoate 250/400 µg once daily in the evening (full dose 500/800 µg) delivered via the Twisthaler device for 14 days.
Placebo	Participants received 2 inhalations of placebo to indacaterol maleate / mometasone furoate once daily in the evening delivered via the Twisthaler device for 14 days.

Measured Values

	Indacaterol Maleate/Mometasone Furoate	Placebo
Number of Participants Analyzed [units: participants]	**14**	**14**
Levels of Plasma Glucose Over Time [units: mmol/L] Mean (Standard Deviation)		
Baseline (N=14, 14)	**5.079 (0.3239)**	**5.157 (0.4415)**
Day 1, pre-dose (N=14, 14)	**5.057 (0.2533)**	**5.236 (0.3855)**
Day 1, 0.25 hours post-dose (N=14, 14)	**5.007 (0.2786)**	**5.264 (0.4069)**
Day 1, 0.5 hours post-dose (N=14, 14)	**4.950 (0.2279)**	**5.207 (0.3385)**
Day 1, 1 hour post-dose (N=14, 14)	**5.036 (0.2620)**	**5.193 (0.3316)**
Day 1, 2 hours post-dose (N=14, 14)	**5.057 (0.2377)**	**5.179 (0.3142)**
Day 1, 4 hours post-dose (N=14, 14)	**7.064 (1.4532)**	**6.793 (1.2344)**
Day 2, 12 hours post-dose (N=14, 14)	**5.221 (0.2326)**	**5.286 (0.3009)**
Day 2, 24 hours post-dose (N=14, 14)	**5.293 (0.4463)**	**5.321 (0.5767)**
Day 14, pre-dose (N=14, 14)	**5.129 (0.4681)**	**5.221 (0.3534)**
Day 14, 0.25 hours post-dose (N=14, 13)	**5.136 (0.4986)**	**4.900 (0.4301)**

Day 14, 0.5 hours post-dose (N=14, 13)	**5.157 (0.4767)**	**4.946 (0.4409)**
Day 14, 1 hour post-dose (N=14, 13)	**5.136 (0.4448)**	**4.962 (0.3841)**
Day 14, 2 hours post-dose (N=14, 13)	**5.093 (0.3269)**	**4.908 (0.4173)**
Day 14, 4 hours post-dose (N=14, 13)	**6.929 (1.3176)**	**7.408 (1.0649)**
End of study (N=14, 13)	**5.257 (0.2821)**	**5.731 (1.0160)**

No statistical analysis provided for Levels of Plasma Glucose Over Time

4. Secondary: Levels of Serum Cortisol Over Time [Time Frame: Baseline; Days 1 and 14 at pre-dose, 0.25, 0.5, 1, 2, 4, 11, 12, 13 hours post-dose; 24 hours post dose (Day 2); study completion (5-9 days after last dose, Day 19-23).]

Measure Type	Secondary
Measure Title	Levels of Serum Cortisol Over Time
Measure Description	At the specified time-points, blood samples were collected for measurement of serum cortisol and the samples analyzed by a central laboratory. The end of study visit was conducted approximately 5-9 days after the last dose.
Time Frame	Baseline; Days 1 and 14 at pre-dose, 0.25, 0.5, 1, 2, 4, 11, 12, 13 hours post-dose; 24 hours post dose (Day 2); study completion (5-9 days after last dose, Day 19-23).
Safety Issue	Yes

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

Reporting Groups

	Description

Indacaterol Maleate/Mometasone Furoate	Participants received 2 inhalations of indacaterol maleate / mometasone furoate 250/400 µg once daily in the evening (full dose 500/800 µg) delivered via the Twisthaler device for 14 days.
Placebo	Participants received 2 inhalations of placebo to indacaterol maleate / mometasone furoate once daily in the evening delivered via the Twisthaler device for 14 days.

Measured Values

	Indacaterol Maleate/Mometasone Furoate	Placebo
Number of Participants Analyzed [units: participants]	**14**	**14**
Levels of Serum Cortisol Over Time [units: mmol/L] Mean (Standard Deviation)		
Baseline (N=14, 14)	**466.214 (178.2311)**	**441.143 (97.5365)**
Day 1, pre-dose (N=14, 14)	**159.643 (100.4533)**	**140.714 (47.2024)**
Day 1, 0.25 hours post-dose (N=14, 14)	**153.786 (87.5313)**	**151.000 (91.2798)**
Day 1, 0.5 hours post-dose (N=14, 14)	**130.143 (74.2375)**	**130.571 (63.6779)**
Day 1, 1 hour post-dose (N=14, 14)	**99.143 (54.5412)**	**131.929 (51.4923)**
Day 1, 2 hours post-dose (N=14, 14)	**65.357 (33.1143)**	**84.286 (27.1220)**
Day 1, 4 hours post-dose (N=14, 14)	**55.929 (24.6716)**	**102.071 (54.8248)**
Day 2, 11 hours post-dose (N=14, 14)	**362.500 (159.3891)**	**478.214 (121.2272)**
Day 2, 12 hours post-dose (N=14, 14)	**289.929 (96.3906)**	**404.214 (123.4623)**
Day 2, 13 hours post-dose (N=14, 14)	**335.214 (150.7811)**	**370.071 (105.2451)**
Day 2, 24 hours post-dose (N=14, 14)	**136.857 (75.4442)**	**193.500 (87.5238)**
Day 14, pre-dose (N=14, 14)	**126.071 (65.6546)**	**122.857 (71.5379)**
Day 14, 0.25 hours post-dose (N=14, 13)	**111.500 (82.9001)**	**127.231 (104.5834)**
Day 14, 0.5 hours post-dose (N=14, 13)	**99.500 (68.5608)**	**121.154 (112.2726)**

Day 14, 1 hour post-dose (N=14, 13)	**82.786 (57.7663)**	**106.385 (118.7936)**
Day 14, 2 hours post-dose (N=14, 13)	**62.071 (44.5861)**	**94.154 (133.8300)**
Day 14, 4 hours post-dose (N=14, 13)	**48.214 (34.5280)**	**102.154 (80.7051)**
Day 15, 11 hours post-dose (N=14, 14)	**242.143 (177.3739)**	**417.000 (100.8312)**
Day 15, 12 hours post-dose (N=14, 13)	**255.500 (154.1442)**	**388.769 (104.6885)**
Day 15, 13 hours post-dose (N=14, 13)	**324.857 (179.8713)**	**385.769 (126.2301)**
End of study (N=14, 14)	**495.286 (259.2054)**	**417.786 (164.1046)**

No statistical analysis provided for Levels of Serum Cortisol Over Time

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Indacaterol Maleate/Mometasone Furoate	Participants received 2 inhalations of indacaterol maleate / mometasone furoate 250/400 µg once daily in the evening (full dose 500/800 µg) delivered via the Twisthaler device for 14 days.
Placebo	Participants received 2 inhalations of placebo to indacaterol maleate / mometasone furoate once daily in the evening delivered via the Twisthaler device for 14 days.

Serious Adverse Events

	Indacaterol Maleate/Mometasone Furoate	**Placebo**

Total, serious adverse events		
# participants affected / at risk	**0/14 (0.00%)**	**0/14 (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 Maleate/Mometasone Furoate	Participants received 2 inhalations of indacaterol maleate / mometasone furoate 250/400 µg once daily in the evening (full dose 500/800 µg) delivered via the Twisthaler device for 14 days.
Placebo	Participants received 2 inhalations of placebo to indacaterol maleate / mometasone furoate once daily in the evening delivered via the Twisthaler device for 14 days.

Other Adverse Events

	Indacaterol Maleate/Mometasone Furoate	**Placebo**
Total, other (not including serious) adverse events		
# participants affected / at risk	**9/14 (64.29%)**	**12/14 (85.71%)**
Eye disorders		
Blepharitis †		

# participants affected / at risk	0/14 (0.00%)	1/14 (7.14%)
Conjunctivitis †		
# participants affected / at risk	0/14 (0.00%)	1/14 (7.14%)
General disorders		
Chest discomfort †		
# participants affected / at risk	0/14 (0.00%)	2/14 (14.29%)
Chills †		
# participants affected / at risk	0/14 (0.00%)	1/14 (7.14%)
Infections and infestations		
Bronchitis †		
# participants affected / at risk	2/14 (14.29%)	0/14 (0.00%)
Nasopharyngitis †		
# participants affected / at risk	1/14 (7.14%)	0/14 (0.00%)
Rhinitis †		
# participants affected / at risk	2/14 (14.29%)	2/14 (14.29%)
Tracheitis †		
# participants affected / at risk	1/14 (7.14%)	0/14 (0.00%)
Investigations		
Peak expiratory flow rate decreased †		
# participants affected / at risk	0/14 (0.00%)	1/14 (7.14%)
Musculoskeletal and connective tissue disorders		
Arthralgia †		
# participants affected / at risk	0/14 (0.00%)	1/14 (7.14%)
Myalgia †		
# participants affected / at risk	1/14 (7.14%)	0/14 (0.00%)

Pain in extremity †		
# participants affected / at risk	**0/14 (0.00%)**	**1/14 (7.14%)**
Nervous system disorders		
Aphonia †		
# participants affected / at risk	**1/14 (7.14%)**	**0/14 (0.00%)**
Headache †		
# participants affected / at risk	**5/14 (35.71%)**	**2/14 (14.29%)**
Syncope vasovagal †		
# participants affected / at risk	**0/14 (0.00%)**	**1/14 (7.14%)**
Tremor †		
# participants affected / at risk	**0/14 (0.00%)**	**1/14 (7.14%)**
Respiratory, thoracic and mediastinal disorders		
Asthma †		
# participants affected / at risk	**0/14 (0.00%)**	**2/14 (14.29%)**
Asthmatic crisis †		
# participants affected / at risk	**0/14 (0.00%)**	**3/14 (21.43%)**
Cough †		
# participants affected / at risk	**5/14 (35.71%)**	**2/14 (14.29%)**
Dyspnoea †		
# participants affected / at risk	**1/14 (7.14%)**	**4/14 (28.57%)**
Painful respiration †		
# participants affected / at risk	**0/14 (0.00%)**	**1/14 (7.14%)**
Oropharyngeal pain †		
# participants affected / at risk	**1/14 (7.14%)**	**0/14 (0.00%)**

Wheezing †		
# participants affected / at risk	**0/14 (0.00%)**	**1/14 (7.14%)**

† 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:	NCT00605306 History of Changes
Other Study ID Numbers:	**CQMF149A2203**
Study First Received:	January 18, 2008
Results First Received:	March 11, 2013
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Health Authority:	France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis)